TABLE OF CONTENTS

SUMMARY

Written by Investigator Medina.

This Level III, Compliance Follow-Up QSIT inspection was conducted at the request of DEN-DO Compliance per FACTS Assignment ID 59574, Compliance Number 8580-0, and was conducted in accordance with C.P. 7382.845, Inspection of Medical Device Manufacturers. Utah Medical Products, Inc. (UTMD) manufactures sterile and non-sterile, non-critical/non-significant risk, Class II, disposable and reusable medical devices for applications in clinical settings as follows: labor and delivery; neonatal/pediatric critical and intensive care; blood pressure monitoring; gynecology (instruments); urology (incontinence); and electro surgery generators and electrodes. UTMD also distributes various OEM products which are not further processed by the firm.

The previous inspection dated 2/24-3/12/2003 was classified [illegible] Corrections, partial corrections, or lack of corrections of the previous FDA-483 items were observed during this inspection and a discussion of these items is contained within this report.

The firm's current operations and/or established procedures were observed during this inspection (but are not limited to) as follows: in-process/finished goods nonconformance handling; CAPA; complaint handling; returned goods authorizations; EtO sterilization; bonding; extrusion molding; injection molding; and production and process controls used in manufacturing of the Deltran and IUP devices. Procedures and associated documentation controlling the quality system and manufacturing procedures were reviewed. Injection molding operations were observed; however, extrusion molding operations were not able to be observed as none was being conducted during this inspection. Procedures and records associated with these operations were also reviewed between 3/12/03 and 2/2/04.

The current inspection found that the firm is operating with continuing cGMP/Quality System Regulations deficiencies with an FDA-483, Inspectional Observations, being issued to the management of the firm at the inspectional closeout. A summary of the items is as follows: a process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures; acceptance procedures to ensure that specified requirements for in-process product are met were not documented; software validation activities for computers or automated data processing systems used as part of production and the quality system have not been documented; the corrective and preventive procedures addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems were not defined; not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified; complaint handling procedures for receiving, reviewing, and evaluating complaints have not been defined; and the device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

A documentary sample (number 68796) was collected to document the manufacturing, sterilization, and interstate shipment of a finished IUP medical device and associated deviations from the Quality System Regulation. Mr. Cornwell reviewed and faxed a copy of the affidavit associated with DOC sample number 68796; however, he stated that he did not have a comment associated with the affidavit and therefore did not sign it.

At the conclusion of the inspection, an FDA-483, Inspection Observations, was issued to and discussed with Kevin L. Cornwell, CEO/Chairman, as well as discussed with Ben Shirley, Quality Manager. The firm did not promise corrections to the items listed upon the FDA-483 and it was not annotated at the request of Mr. Cornwell. No refusals were encountered during this inspection.

Post-inspectional correspondence, including the FMD-145, should be directed to Kevin L. Cornwell, CEO/Chairman, Utah Medical Products, Inc., 7043 South 300 West, Midvale, Utah 84047.

ADMINISTRATIVE DATA

Written by Investigator Medina.

Inspected firm:	Utah Medical Products, Inc
Location:	7043 South 300 West Midvale, UT 84047-1048
Phone:	(801) 566-1200
FAX:	(801) 566-1328
Mailing address:	7043 South 300 West Midvale, UT 84047
Dates of inspection:	2/2/2004, 2/3/2004, 2/4/2004, 2/5/2004, 2/6/2004, 2/7/2004, 2/9/2004, 2/10/2004, 2/11/2004, 2/12/2004, 2/17/2004, 2/23/2004, 2/24/2004, 2/25/2004, 2/26/2004, 2/27/2004, 3/1/2004, 3/2/2004, 3/3/2004
Days in the facility:	19
Participants:	Lori A. Medina, Investigator Ralph W. Jerndal, Investigator Monica J. Wilkins, Investigator

This inspection was not pre-announced by the Investigator team which consisted of the individuals mentioned above. On 2/2/04, FDA-482, Notice of Inspection, was issued and credentials displayed to Kevin L. Cornwell, CEO/Chairman. Mr. Cornwell was the only individual present at the firm that the Investigational team had contact with on the first day of the inspection.

Mr. Cornwell accepted the FDA-482 on 2/2/04 and introduced Ben Shirley, Quality Manager, on 2/3/04. The two responsible individuals present during the inspection were Mr. Cornwell and Mr. Shirley. Mr. Shirley was present for the entire duration of the inspection with the exception of 2/2/04 and 2/17/04. [redacted], was present as an observer during this inspection and was allowed to be present by Mr. Cornwell. [redacted] provided general information associated with risk management and was present sporadically throughout this inspection. Investigators Medina, Wilkins, and Jerndal were present on each day of the inspection with the exception that on 2/17/04, Investigator Jerndal was not present.

On 3/3/04, a FDA-483, Inspectional Observations, was issued to Mr. Cornwell in the presence of Mr. Shirley. Daily inspectional summaries and the inspectional close-out on 3/3/04 were audio tape recorded as Mr. Cornwell requested to tape record these meetings. The FDA copies of these tape recorded meetings are found as Exhibit L1 and are attached to the original EIR only.

All information and records were provided by Mr. Shirley, unless stated otherwise.

Utah Medical Products, Inc. (UTMD) routinely operates [redacted] days a week which accounts for a [redacted] of the firm's operational capacity. Office hours are Monday-Friday, 7:00 a.m.-5:00 p.m. There are approximately [redacted] employees at the Midvale, Utah facility.

UTMD is currently registered for 2004 with FDA as a medical device manufacturer, contract manufacturer, specifications developer, repacker/relabeler, and initial distributor which is found as Exhibit L2. Currently, the firm is not seeking any additional medical device approvals (in the form of 510(k)s or PMAs).

Individual sections of this Establishment Inspection Report (EIR) are identified by author.

HISTORY

Written by Investigator Medina.

The firm's history of business remains the same as it was reported in the March 2003 EIR.

Exhibit L3 is a current organizational chart (no individual names are included within this chart as Ben Shirley, Quality Manager, stated that it is against the firm's policy to provide individual names of firm employees). Exhibit L4 is a current QUALITY MANUAL. A current floor plan of the facility is found as Exhibit L5.

During the inspectional close-out, Mr. Cornwell provided the firm's current ISO registrations as follows:

EXHIBIT	ISO DOCUMENT
L6	Certificate of Registration of Quality System to ISO 13485:1996 under CMDCAS and I.S EN ISO 9001:1994. X ~~~~~~~~~~ X. X~~~X provided said certification; Certificate Number X~~~X Registration Date X~~~X. Remains valid until X~~~X
L7	Attachment 1 to Certificate number X~~~X which includes the scope and date of the audit X~~~~X
L8	Certificate of Registration of Quality System to I.S. EN ISO 13485:2000 (based on and including ISO 9001:1994). X ~~~~~~~~~~ X X~~~~~~X provided said certification; Certificate Number X~~~~X Registration Date X~~~X; Remains valid until X~~~X

A 2002 UTMD Annual Report is found as Exhibit L9 and was provided by Mr. Cornwell.

Exhibit L10 is the firm's response to the previous FDA-483 (dated 3/12/03) which was drafted, compiled, and provided to the current Investigator team during the current EI on 2/23/04. Exhibit L10a is the firm's cover letter dated 4/11/03 sent to the FDA Denver District Office from Mr. Cornwell in response to the FDA-483 issued to the firm on 3/12/03.

INTERSTATE COMMERCE/JURISDICTION

Written by Investigator Medina.

Annual sales of UTMD manufactured products continue to be approximately [illegible] according to Mr. Cornwell. Approximately [illegible] of the finished devices continue to be distributed within interstate commerce (outside the state of Utah). Promotion of medical devices continues to include a national direct sales force, promotional catalogs, and the via use of the world wide web on the internet (www.utahmed.com). Additionally, the firm utilizes [illegible]

The firm ships finished devices to locations within the United States via [illegible] DOC sample number 68796 was collected to document the manufacturing, [illegible]sterilization, and interstate shipment of a finished IUP medical device.

Utah Medical Products, Inc. (UTMD) manufactures sterile and non-sterile, non-critical/non-significant risk, Class II, disposable and reusable medical devices for applications in clinical settings as follows: labor and delivery; neonatal/pediatric critical and intensive care; blood pressure monitoring; gynecology (instruments); urology (incontinence); and electro surgery generators and electrodes. UTMD also distributes various OEM products which are not further processed by the firm. The firm manufactures and distributes approximately [illegible] injection molded parts to OEMs (medical device and non-medical device related manufacturing facilities).

Representative promotional materials were obtained during the current inspection and a summary is as follows:

EXHIBIT	DEVICE PROMOTIONAL MATERIAL
L11	**LABOR AND DELIVERY: Reducing Maternal and Fetal Mortality** which contains information associated with the device lines as follows: [illegible]

L12	**NEONATAL AND PEDIATRIC INTENSIVE CARE** which contains information associated with the device lines as follows: Umbili-Cath (complete umbilical catheter family); Picc-Nate (peripherally inserted central catheter); catheterization tray (general procedure tray); nutri-cath (silicone long-term enteral feeding catheter); hemo-nate (18 micron filtration system); disposa-hood (disposable infant respiratory hood); Uri-Cath (closed urinary drainage system for the neonatal/pediatric patient); Dialy-Nate (neonatal/pediatric disposable peritoneal dialysis set); Pala-Nate (silicone orotracheal protection device for neonates); Myelo-Nate (neonatal/pediatric CSF sampling kit); Thora-Cath (silicon chest drainage catheter); and Deltran-Plus (closed needleless arterial blood collection system).
L13	**DELTRAN** which contains information associated with the device lines as follows: Deltran IV (complete pressure transducer system); Deltran I (pressure transducer); Accessories and Kits (Delta-Flow waveform accuracy; The Organizer; monitoring kits; Delta-Cal system verification); and Deltran-Plus (needleless arterial blood collection system).
L14	**GYNECOLOGY PRODUCTS CATALOGUE** which contains information associated with the device lines as follows: gynecology electrodes (Letz/UtahLoop and conization); specialty electrodes (optimicro needle; epitome scalpel; and external lesion); electrosurgical generators (Finesse and Finesse II); smoke evacuation (Filtresse and smoke evacuation wand); filtration kits; electrosurgery accessories (filter pack; footswitches; internal filters; dispersive pads; electrosurgery pens; and fuses); ES/GYN instruments (lateral vaginal retractor; speculum; tenaculum; forceps; and specula – Graves; Collin; Pederson; Weisman-Graves; and disposable); endometrium assessment; and other gynecology products (Liberty and Pathfinder Plus).
L15	**ELECTROSURGERY PRODUCTS CATALOGUE** which contains information associated with the device lines as follows: gynecology electrodes (Safe-T-Gauge and Tungsten Wire); C-Letz Conization electrode; Letz electrodes; specialty electrodes (Utah Optimicro Needle; External Lesion; and Epitome); electrosurgical generators (Finesse and Finesse II); smoke evacuation (Filtresse; smoke evacuation wand; and smoke evacuation filters); electrosurgery accessories (filters; internal filters; dispersive pads; footswitches; fuses; and electrosurgery pens); Electrosurgical instruments (Graves speculum; Collin speculum; Schroeder tenaculum; Pederson speculum; disposable speculum; Kogan Endocervical speculum; Graves Wide view speculum; Weisman-Graves speculum; lateral vaginal retractor); and Four-Way Vaginal Expanders.

According to Mr. Cornwell, the most widely distributed devices continue to include:

[redacted]

RESPONSIBILITY

Written by Investigator Medina.

Mr. Cornwell accepted the FDA-482 on 2/2/04 and introduced Ben Shirley, Quality Manager, on 2/3/04. The two responsible individuals present during the inspection were Mr. Cornwell and Mr. Shirley. Mr. Shirley was present for the entire duration of the inspection with the exception of 2/2/04 and 2/17/04. [redacted] was present as an observer during this inspection and his presence was permitted by Mr. Cornwell. [redacted] provided general information associated with risk management. [redacted] was present sporadically throughout this inspection. Investigators Medina, Wilkins, and Jerndal were present on each day of the inspection with the exception that on 2/17/04, Investigator Jerndal was not present.

Daily inspectional summaries and the inspectional close-out on 3/3/04 were audio tape recorded as Mr. Cornwell requested to tape record these meetings. The FDA copies of these tape recorded meetings are found as Exhibit L1 and are attached to the original EIR only.

Mr. Shirley provided requested documentation, answered questions, and provided tours of the facility. Mr. Cornwell was present at the initiation of this inspection and during the daily summary meetings to discuss activities of the day and inspectional findings (these meetings were audio tape recorded). Mr. Cornwell provided information associated with the firm's complaint handling system; history of business; and inspectional responses to the previous FDA-483 dated 3/12/03.

On 3/3/04, a FDA-483, Inspectional Observations, was issued to Mr. Cornwell in the presence of Mr. Shirley. Mr. Cornwell also had individuals connected via telephone as follows: Larry Pilot, Attorney; Dan Jarcho, Attorney; and [redacted]

KEVIN L. CORNWELL is the Chief Executive Officer (CEO)/Chairman of the Board: Mr. Cornwell is also the firm's President and Secretary, and is involved in the day-to-day operations of the firm. Mr. Cornwell is a member of the Materials Review Board and the Clinical Review Board and he participates in the firm's corrective and preventive action issues, complaint review, MDR decisions, and tracking/trending of quality data. Mr. Cornwell reports directly to the Board of Directors.

BEN SHIRLEY is the Quality Manager/Vice President of Engineering: Mr. Shirley directs engineering with regards to product development and design control and participates in the engineering activities involved with product manufacturing and complaint evaluations. Since the previous inspection, Mr. Shirley has become the Quality Manager and the firm's Quality Management Representative. Additionally, since the previous inspection, Mr. Shirley has become an officer of the company (Vice President of Research and Development) as mentioned in the 2002 Annual Report. Mr. Shirley reports to Mr. Cornwell and was present each day of the inspection except for 2/17/04. He answered questions, provided documentation as requested, and provided tours of the facility.

It was observed that Kevin L. Cornwell, CEO, has the duty, responsibility, and power to detect, prevent, and correct violations of the Quality Systems Regulation. This was demonstrated when Mr. Cornwell instructed Ben Shirley, a member of the Management Team, to entertain the FDA inspection and to provide all of the requested information to United States Government Officials. Additionally, Mr. Cornwell signed the firm's Quality Policy/Mission statement as found within the current version of the firm's Quality Manual (Exhibit L4, Page 2).

Exhibit L3 is a current organizational chart (no individual names are included within this chart as Ben Shirley, Quality Manager, stated that it is against the firm's policy to provide individual names of firm employees).

Exhibit L10, Pages 12-17 is SOP. entitled "HUMAN RESOURCES ADMINSTRATION", Revision dated which contains employee job descriptions for the positions (but not limited to) as follows: Chief Executive Officer; Chief Administrative Officer; Human Resources Specialist/Manager; Chief Financial Officer; Product Development Manager; Product Development Engineer; Manufacturing Manager; Manufacturing Engineer; Production Supervisor; Outside Sales Manager; Sales Representative; International Sales Manager; Customer Service Supervisor/Manager; Product Manager; Materials/Production and Inventory Control/Distribution Manager; Distribution Supervisor; Materials Buyer/Planner; Production Planning and Control Manager; Quality Assurance Manager; and Quality Engineer.

A 2002 UTMD Annual Report is found as Exhibit L9 and was provided by Mr. Cornwell. At the time of this inspection, the 2003 Annual Report had not yet been completed. The 2002 Annual Report identifies the individuals currently holding positions on the Board of Directors and Officers as follows:

BOARD OF DIRECTORS

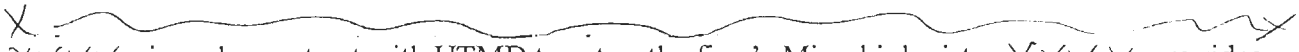
OFFICERS

Kevin L. Cornwell, President and Secretary

Paul O. Richins, Vice President and Chief Administrative Officer

Greg A. LeClaire, Chief Financial Officer

Ben Shirley, Vice President of Research and Development



[redacted] is under contract with UTMD to act as the firm's Microbiologist. [redacted] provides opinion on sterilization issues including bioburden testing, sterilization validation, comparative resistance testing, packaging validation, and shelf-life studies. He was present on 2/12/04 and provided answers to Investigator Wilkin's questions associated with [redacted] sterilization of the firm's products. Additionally, [redacted] performs laboratory testing in the aforementioned areas.

There are no labeling agreements present at the firm.

Post-inspectional correspondence, including FMD-145, should be directed to Kevin L. Cornwell, CEO/Chairman located at Utah Medical Products, Inc., 7043 South 300 West, Midvale, Utah 84047.

MANUFACTURING / DESIGN OPERATIONS

Written by Investigator Medina.

The device manufacturing operations which were presented in the previous EIR (dated 2/24-3/12/03) remain relatively unchanged.

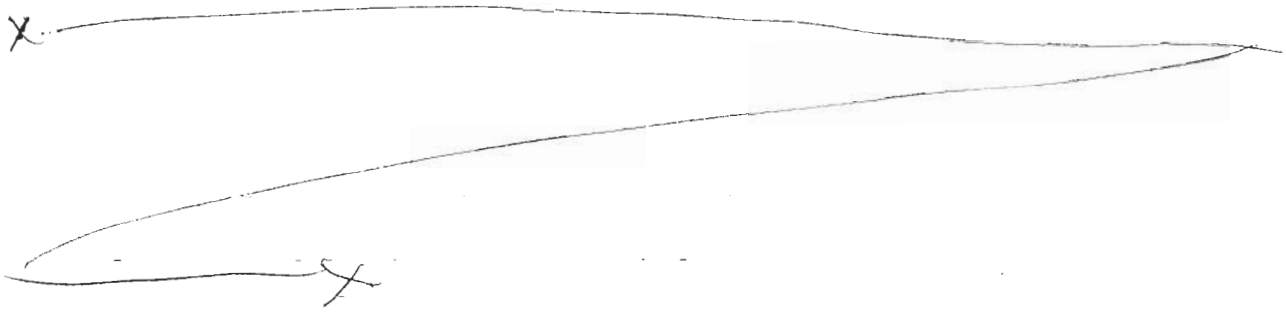
The facility is a company owned, two-story building located in a business/industrial park in Midvale, Utah.

A current plant floor plan is found as Exhibit L5.

General business operational areas of the facility are as follows:

Operations as associated with finished device manufacturing are as follows:

The injection and extrusion molding area continues to be a class clean room. There are injection molding machines, extruder, and automated stopcock assembly machine located within this area.



Sterile products are processed utilizing sterilization by the firm to be performed at

Injection molding operations were observed during this inspection. Extrusion equipment was observed; however, it was not operational as the firm was not producing extruded parts during the current inspection.

Documents reviewed in the *Management Responsibility* subsystem included: Quality Plan, Internal Audit SOP and audit plans, and the agenda for the 2003 end of year management review meeting. For the specific documents reviewed under this section refer to the Management Controls Subsystem written by Investigator Wilkins, which is included in this section of the report.

For the documents reviewed in the *Design Control* subsystem refer to the section written by Investigator Wilkins included in this section of the report.

Documents reviewed in the *Production and Process Control* subsystem included review of device history records (DHR) for IUP and Deltran units.

Processes and records reviewed included sterilization validation (Investigator Wilkins), environmental monitoring procedures and data reports (Investigator Wilkins), comparative resistance studies (Investigator Wilkins), accelerated aging packaging validation (Investigator Wilkins), real time packaging studies (Investigator Wilkins), and software validations (Investigator Medina and Investigator Wilkins). Qualification efforts associated with extrusion molding (Investigator Jerndal), injection molding (Investigator Medina), annealing injection molded parts (Investigator Medina), and bonding (Investigator Jerndal) were reviewed. The Production & Process Controls Subsystem subsection included in this section of the report describes the documents and processes covered by Investigator Wilkins.

Documents reviewed in the *Corrective and Preventive Action* subsystem included SOPs for Corrective and Preventive Actions, Consumer Complaints, Complaint Investigations, Non-conforming Materials (NCMR), and Returned Goods (RGA). Other documents reviewed included tracking of quality data including corrective and preventive actions, complaints, scraps, NCMRs, and some product reject data. MDRs and consumer complaints were reviewed as were NCMRs and RGAs. Meeting minutes were provided for the Materials Review Board and/or Corrective and Preventive Action meetings to determine what kind of quality data were being tracked. The Corrective & Preventive Action Subsystem subsection included in this section of the report describes the documents and processes covered by Investigator Wilkins.

The firm does not make any devices subject to Tracking requirements. There were no corrections and removals and the firm had not conducted a recall since the close-out of the previous inspection dated 3/12/03, according to Mr. Cornwell.

The following sections were written by Investigator Wilkins:

Management Controls Subsystem

I, Investigator Wilkins, reviewed the following procedures and records during the review of the Management Controls Subsystem:

- Utah Medical Products, Inc. Quality Manual, Revision Revision Date refer to Exhibit #M72
- Quality Policy
- Quality Plan
- Management Review of Quality System procedure, Document No. , Revision Revision Date , refer to Exhibit #M124
- Management Review Agenda for meeting held on
- Risk Management procedure, Document No. Revision Revision Date refer to Exhibit #M125
- Human Resources Administration Directive, Document No. , Revision Revision Date

Observations were not identified for the records reviewed under this subsystem.

Design Controls Subsystem

I, Investigator Wilkins, reviewed the following procedures during the review of the Design Controls Subsystem:

-
- Directive for the Development of Products, Product Development Directive, Document No. , Revision Revision Date
-
- Risk Analysis procedure, Document No. , Revision Revision Date refer to Exhibit #M126
- Risk Analysis Form Specification, Document No. Revision Revision Date
- Guidelines for Writing Test Protocols procedure, Document No. , Revision Revision Date

- Sterile Packaging Design procedure, Document No. XXXX , Revision X Revision Date XXXX
- Software Development Validation and Documentation, Document No. XXXXX, Revision X, Revision Date XXXX
- Project Checklist Form Specification, Document No. XXX Revision X, Revision Date

- Change Proposals Directive, Document No. XXXXX , Revision XRevision Date
- Controlled Document Paper Copies, Document No. XXXXX Revision XRevision Date

After a review of the procedures, I, Investigator Wilkins, requested a list of the design changes for the Intran Plus products for the period between X There was only XX change to the IUP product line, so I reviewed the Change Proposal record.

During this inspection period and in order to sample additional records, I reviewed Change Proposal records and one Design History File with Design Review for the X X Based on the records reviewed, observations were not identified.

Observations were not identified for the records reviewed under this subsystem.

Corrective & Preventive Action (CAPA) Subsystem

I, Investigator Wilkins, reviewed the following procedures during the review of the CAPA Subsystem:

- Customer Complaint System, Document No. XXXX Revision Revision Date XXXX, refer to Exhibit #M26
- Customer Complaint Investigation, Document No. XXXXX, Revision X Revision Date XXXX refer to Exhibit #M27
- Post Distribution Monitoring, Document No. XXXX , Revision X Revision Date XXXX refer to Exhibit #M28
- Corrective and Preventive Action (CAPA) procedure, Document No. XXXX Revision X Revision Date XXXX
- NonConforming Materials procedure, Document No. XXXXX Revision X Revision Date XXXX
- NonConforming Materials procedure, Document No XXXXX , Revision X Revision Date XXXX

- Risk Management procedure, Document No. XXX Revision X Revision Date , refer to Exhibit #M126
- Risk Management Plan Form Specification, Document No. XXX Revision X, Revision Date XXX
- Risk Analysis procedure, Document No. XXXX, Revision X, Revision Date XXXX, refer to Exhibit #M126
- Risk Analysis Form Specification, Document No. XXX Revision X Revision Date
- Risk Assessment procedure, Document No. XXXX, Revision X Revision Date XXX , refer to Exhibit #M127
- Risk Assessment Form Specification, Document No. XX , Revision X, Revision Date XXX

On 02/03/04, I, Investigator Wilkins, requested the logs or spreadsheets for complaint records, nonconforming material reports, Corrective Action Reports, and Deviation Waivers. I, reviewed the logs/spreadsheets on the evening of 02/03/04.

On 02/04/04, we requested complaint records for review for the following product categories:

- Intran Plus
- ESU Sterile Accessories
- Loop/Ball
- Finesse

From the X complaints received for the period between X ——— X, we reviewed X complaints, of which, I, Investigator Wilkins reviewed X complaint records. For additional information and discussion, refer to the Objectionable Conditions section of the report.

On 02/04/04, we requested to review the Nonconformance Material Reports initiated since the last inspection, between the period of X ——— X, for the following nonconformance categories:

- Sterilization
- Contamination
- Functional/Functional Defect
- Other selected categories

PURGED

From the XX NCMR' received for the period between X ——— X, we reviewed XX NCMR's, of which, I, Investigator Wilkins reviewed X NCMR records.

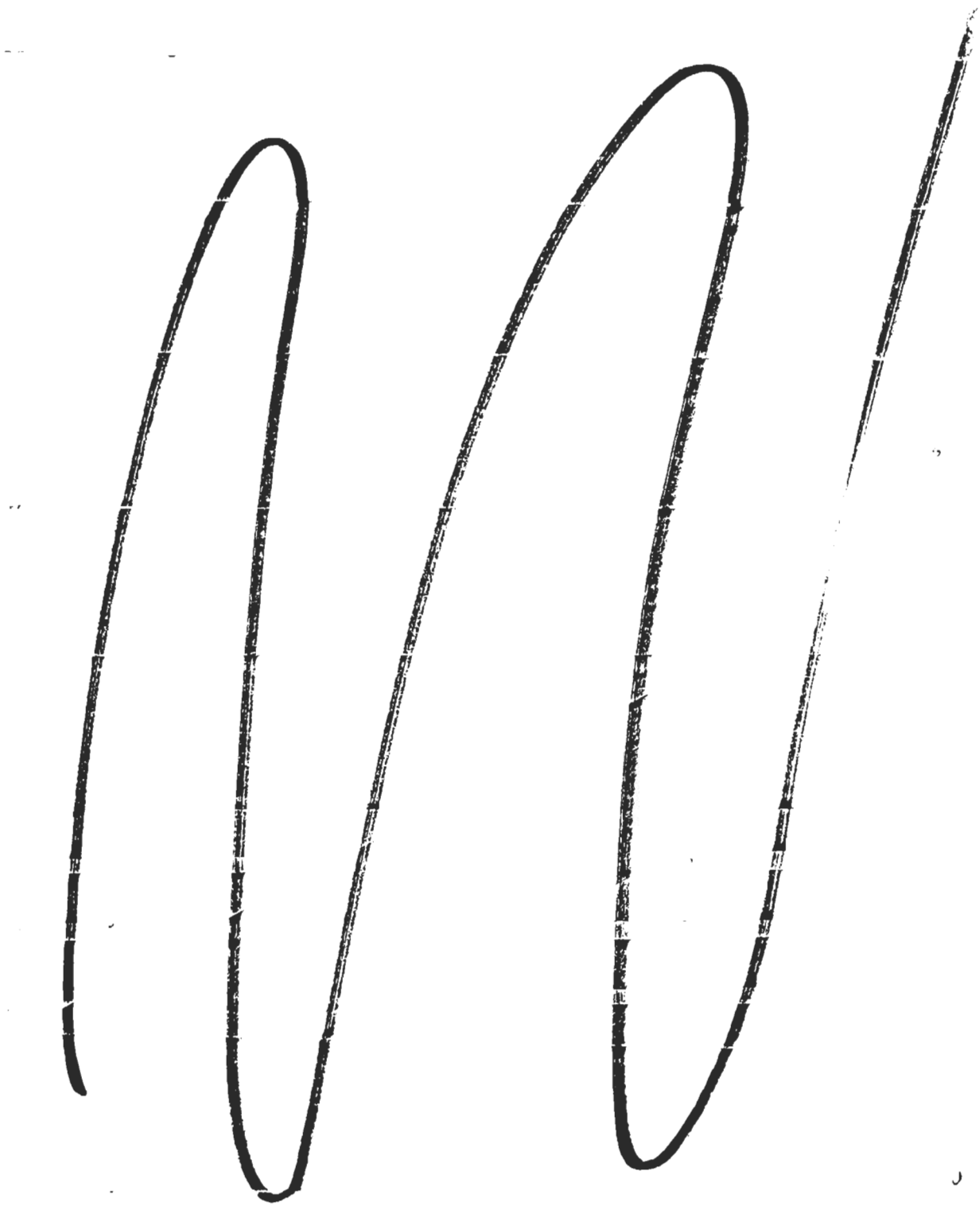
In addition, On 02/04/04, we requested to review all the Corrective Action Reports initiated since the last inspection, for the period between X ——— X . Of the X CA/CAR records initiated, we reviewed X CA's/CAR's, of which, I, Investigator Wilkins reviewed X Corrective Action files.

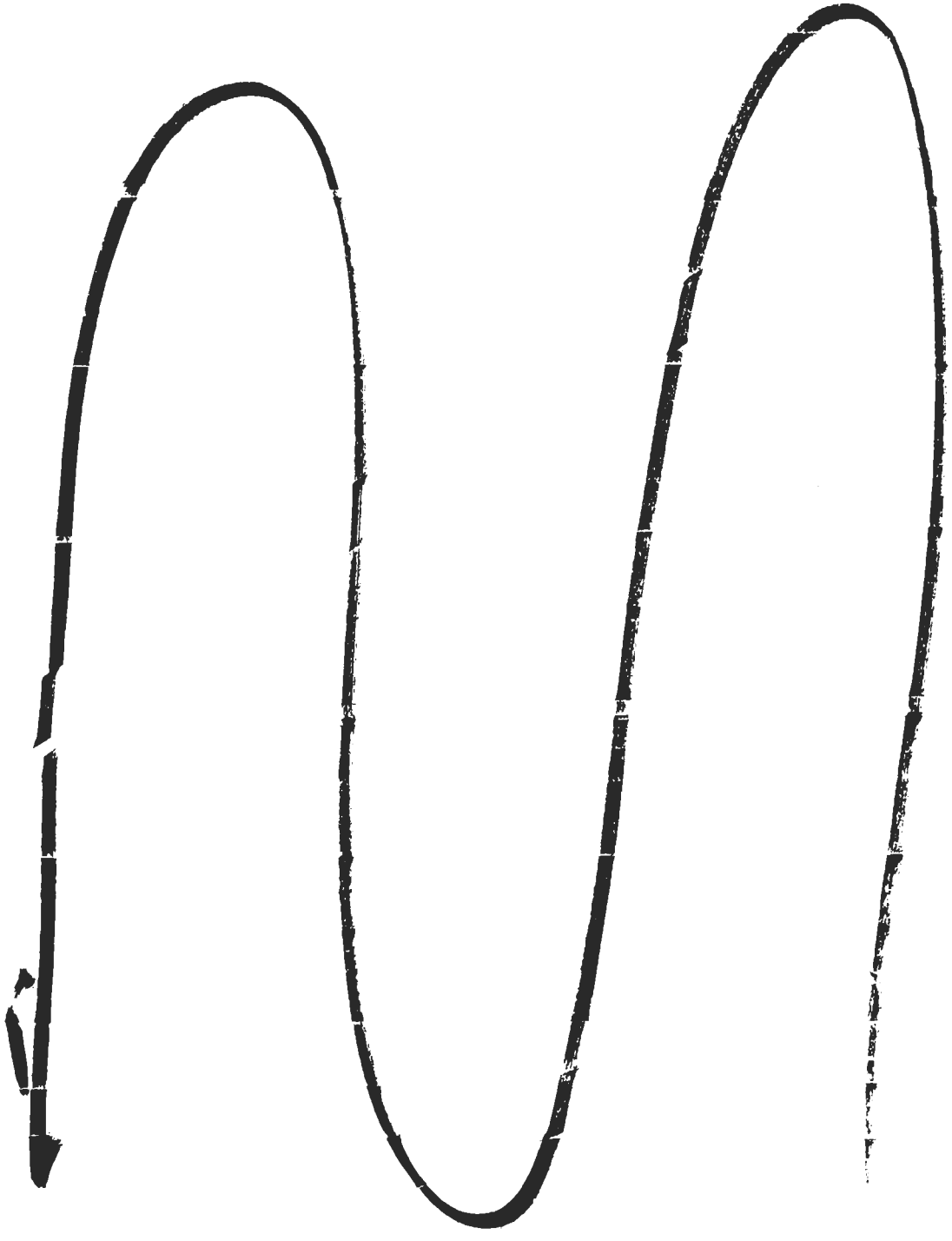
I, Investigator Wilkins, also reviewed the XX files that were reported as Medical Device Reports and XX files in which the company received as MedWatch reports; but, which were not reported as MDR's, refer to Exhibit #M98 Page 1 and Exhibit #M98 Page 2, respectively. A review of the records revealed that X MDR was submitted approximately XX days after the 30 day reporting requirement, for additional information on this item refer to the Voluntary Corrections section of this report. This item was not included as an observation on the FDA-483 form, but was discussed with the company's management.

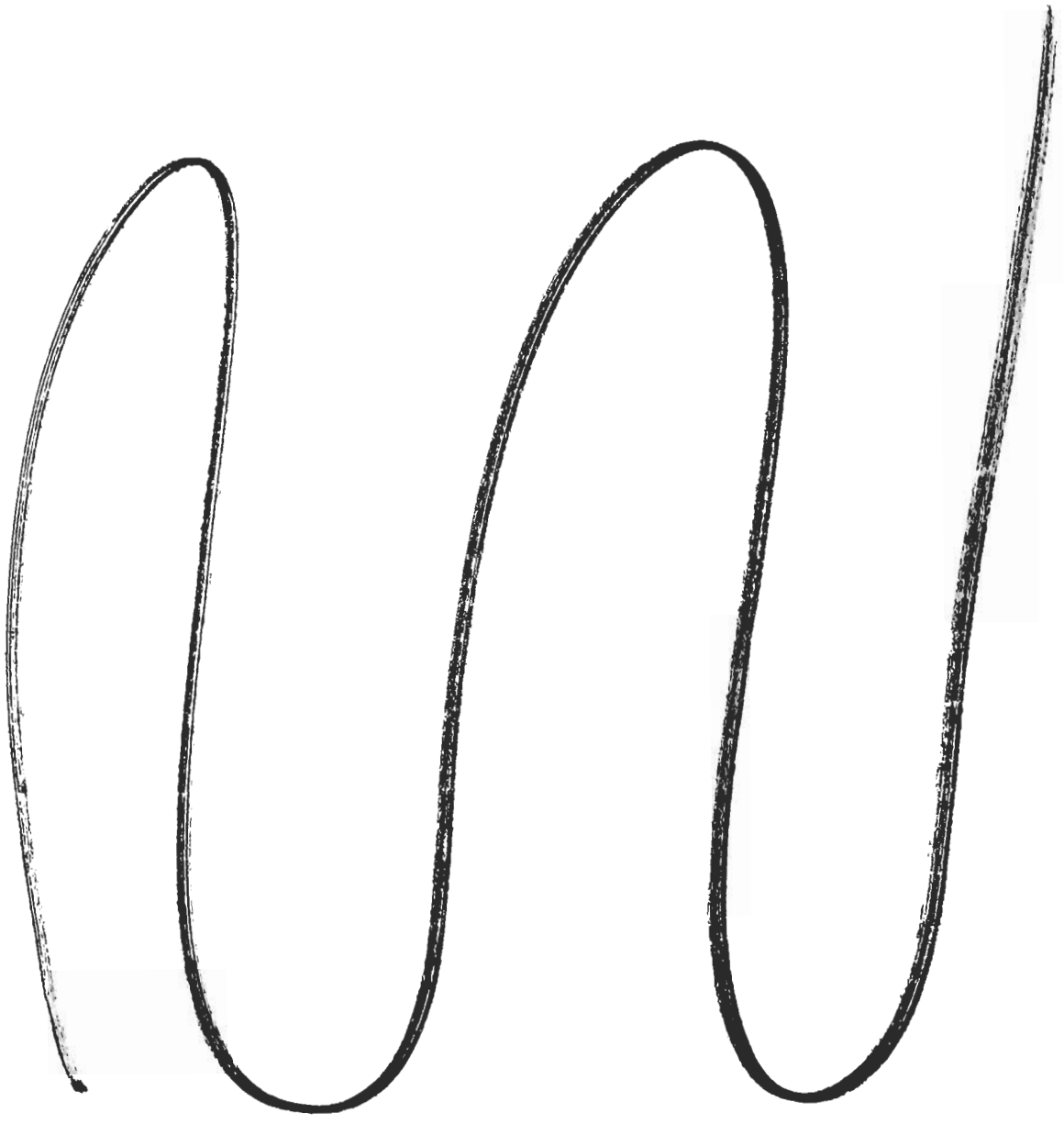
Documentation errors were discussed with management, but were not cited on the FDA-483, which included issues as incorrect dates entered, lack of an actual signature instead of a typed signature, and lack of reference to quality data related to the corrective action or investigation, but the data was available. Two observations were cited in reference to the CAPA and Complaint Handling Procedures, refer to the Objectionable Conditions section of this report.

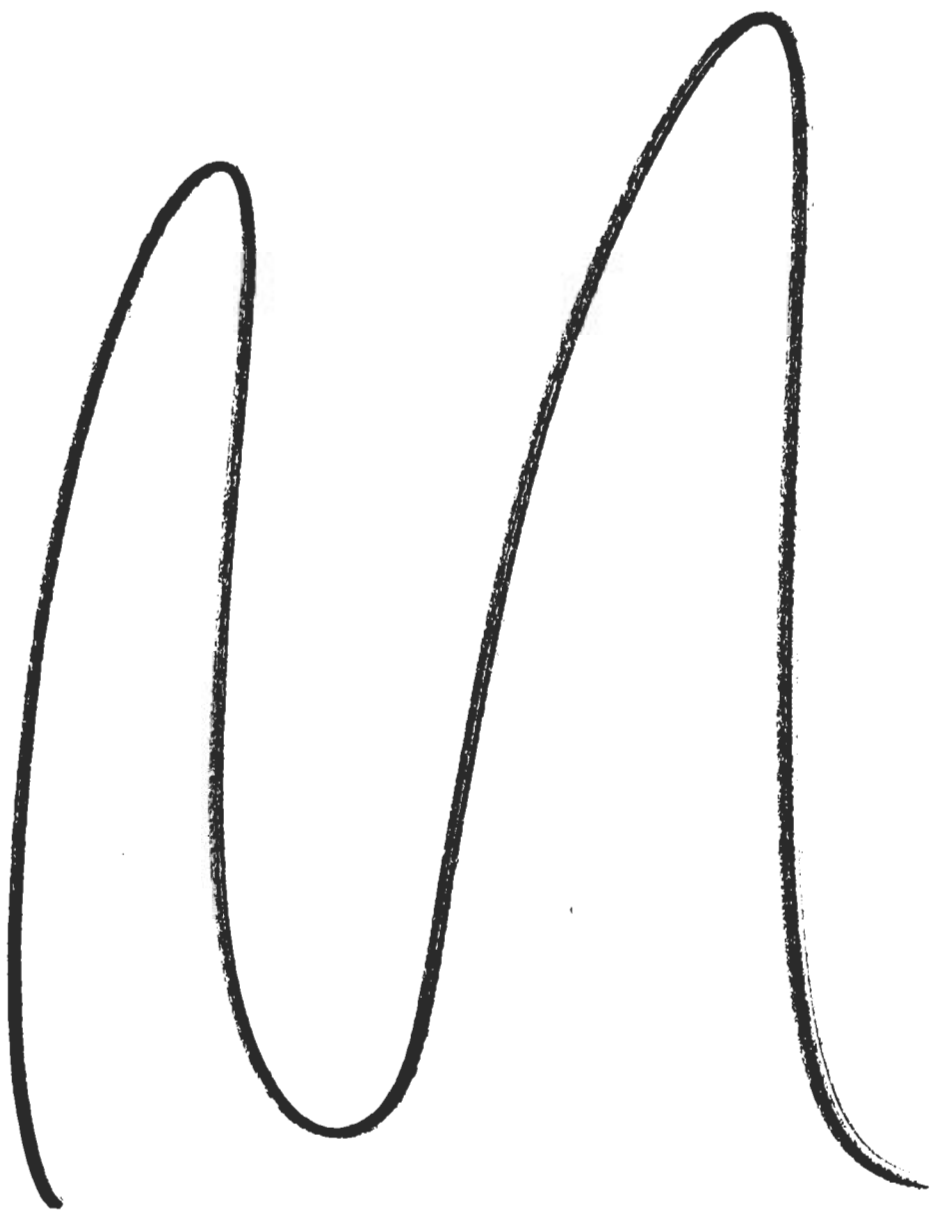
Production & Process Controls Subsystem

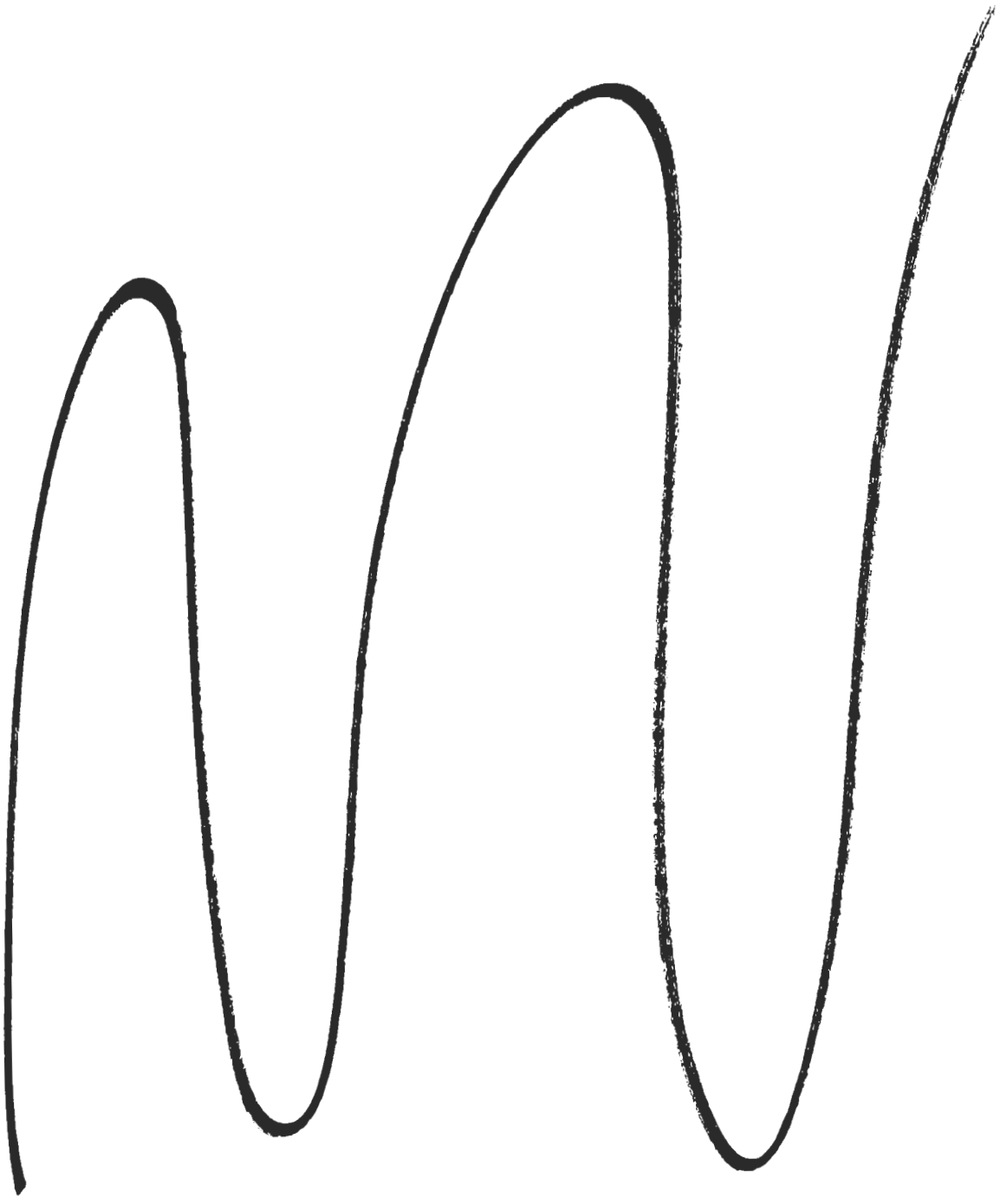
I, Investigator Wilkins, reviewed the following procedures and records during the review of the Production & Process Controls Subsystem:

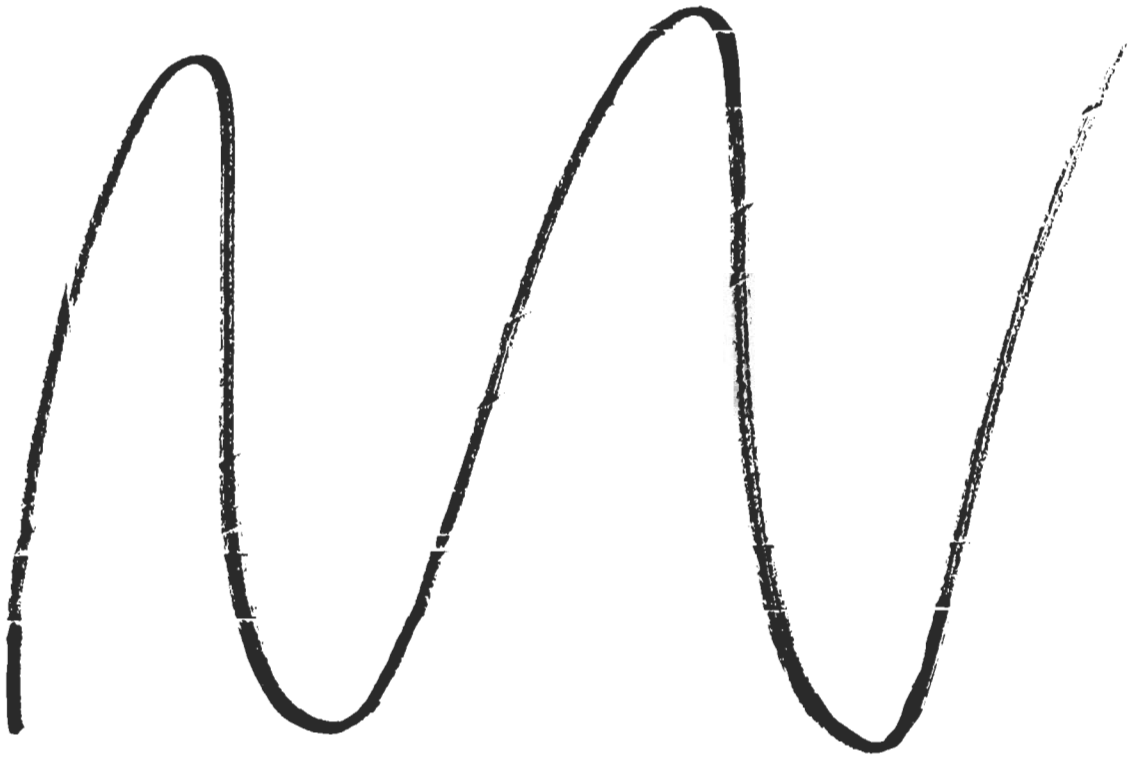








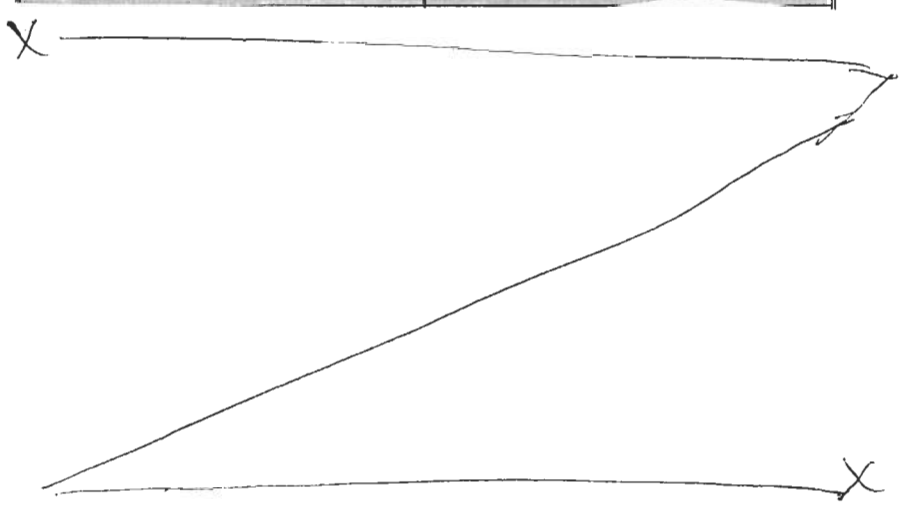




In addition, I, Investigator Wilkins, reviewed the following Sterilization Cycle and Device History Records (Lot History Records):

STERILIZATION PROCESS CYCLE RECORDS (DHR'S)

PROCESS/RETORT NO.	DATE



The sterilization cycle process/retort records identified and included documentation of the product lot history numbers sterilized. During the review of the sterilization process cycle records (process/retort records), I selected the lot history records identified below for review.

I, Investigator Wilkins, reviewed DHR's lot history records for various devices because they were selected for review in relation to the sterilization cycle records instead of a specific device. The following DHR's were reviewed for devices manufactured between the period of X——X X——X

DEVICE HISTORY RECORDS

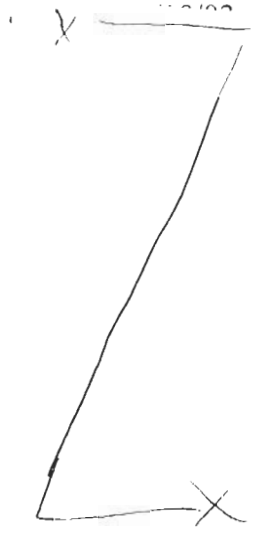
LOT NUMBER	PRODUCT NUMBER	Product Name
X		

LOT NUMBER	PRODUCT NUMBER	Product Name

For the period between , I, Investigator Wilkins, also reviewed the Environmental Monitoring procedures and tests conducted at a scheduled frequency. The following environmental test results, reports and data were reviewed:

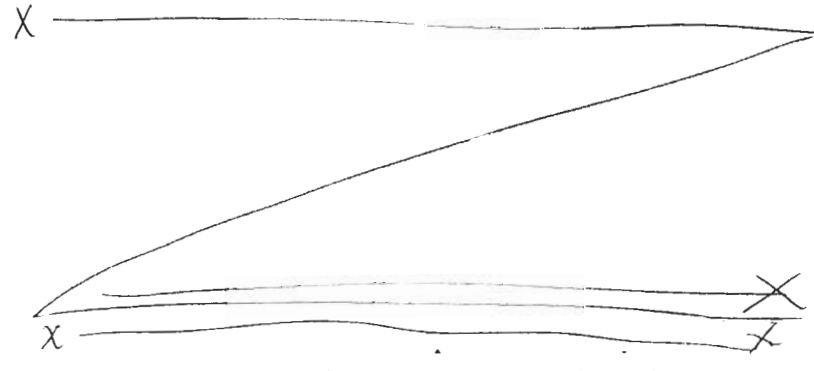
- Test Results for Monitoring of

- Molding Area Environmental Monitoring of

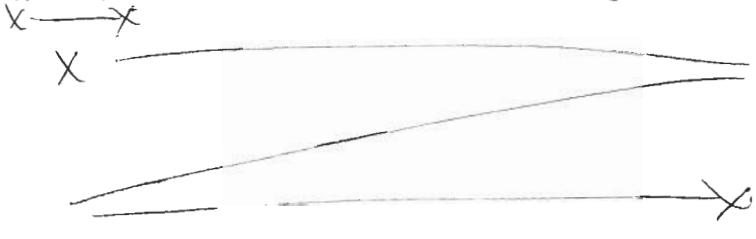


- Passive Environmental Air Monitoring

- Bioburden Monitoring of Products.



- Active Air Environmental Monitoring with



The Voluntary Corrections section of the report includes additional information in relation to some of the processes or items identified above, which were covered by Investigator Wilkins.

MANUFACTURING CODES

Written by Investigator Medina.

Exhibit L16 is a procedure entitled "LOT NUMBER FORMAT", Revision X dated X—X which defines the format to be utilized in the Lot Number System at the firm. X ——— X addresses manufactured parts (finished goods) lot numbers and X ——— X addresses serial numbers as associated with finished goods. A summary of these coding systems is as follows:

MANUFACTURED PARTS:

X ——— X

SERIAL NUMBERS:

X ——— X

COMPLAINTS / PRODUCT DEFECTS

Written by Investigator Medina.

The CDRH MAUDE database revealed MDRs (on 1/7/04) as follows:

X ——— X

PURGED

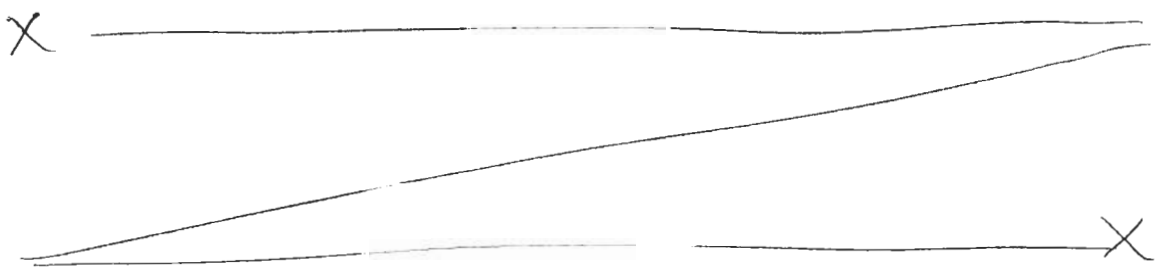
EXTRUSION MOLDING OPERATIONS

Written by Investigator Jerndal.

Since Utah Medical has operated Peripheral equipment, includes a There was no extrusion molding in progress during the two times observed during this inspection, namely According to Mr. Shirley, they did run The equipment appeared to be clean and in good repair. Calibration stickers were observed variously such as on the laser micrometer, cutter feed controller, water temperature, vacuum pHs and so on. The firm has recently from the same company and of the same type, that according to Mr. Shirley, they intended to use with a The firm uses a stand-alone These units can be used with According to Mr. Shirley. Calibration stickers were observed on the equipment.

Exhibit R1 is a list of the parts produced by extrusion molding at this facility with the above-described equipment. illustrated in the Exhibit L11, "Labor and Delivery Products" brochure. Since, this firm has produced batches of this part, approximately units per batch, with an approximate run time per batch . The part catheter product. Production numbers for this part therefore will be approximately equal to production numbers for the ' is the catheter body tubing for the fluid-filled IUPC Intrauterine Pressure Catheter device, also illustrated in Exhibit L11. batch of approximately of this catheter body component was produced manufactured at approximately according to Mr. Shirley. None of this part has been extruded since

I reviewed the Device History Records for the batches of product produced by extrusion molding since , for the part , comprising approximately production during this period. When not in use, the extrusion equipment is The Device History Records for these batches are attached as exhibits as follows:



These work orders comprise all of the extrusion performed since for the Part . The firm also produced batch of during this inspection and I reviewed the Device History Record for that batch also, and it is included here as Exhibit R5, a batch of units of the introducer polypropylene, work order , start date

For all parts produced, production consists of followed by . for further processing. Testing **consists** of dimensional checks performed on samples pulled as Dimensional checks are performed at . selected for testing. For example, the current sampling scheme for For the Exhibit R3. part batch, work order units were sampled for this testing during the batch run. (Note that the firm's previous sampling schedule for this part was to pull For this batch run, the operator failed to adhere to the now current scheme of and took samples every apparently reverting to the older sample scheme. The firm initiated a process deviation in response to my bringing this to their attention.) In practice then, the number of samples taken over a batch run of this size for this part would more typically be larger, perhaps closer to units sampled.

These parts are also subject to additional testing during further production that occurs at this facility utilizing these parts. For example, with the selection for review during this inspection, each of the parts undergoes prior to use in production. This will be discussed in more detail below under the sub caption "INTRAN PLUS Assembly and Work Order Review". Note that the testing of these parts was not offered by Mr. Shirley as part of the rationale for their position, that this extrusion process does not require validation, rather, I encountered this testing during a review of production and testing procedures for the INTRAN Plus IUP device.

On the firm introduced Change Proposal (CP) , submitted This CP affected the majority of procedures previously in place, directing the This CP is attached here as Exhibit R6. Page 1 lists the documents affected and their revision changes. The CP attaches copies of the previous, and the new, revisions of the majority of the listed documents. Primary changes enacted with this CP include, This is the product sampling performed during extrusion batch runs described above. This CP also introduces the

change in sample scheme from [illegible] According to Mr. Shirley, setup parameters, now under document control as setup sheets [illegible] have not changed fundamentally since the processes for each part were first introduced many years ago. The other procedural changes made as part of this change proposal are [illegible] According to Mr. Shirley, apart from the change in sampling scheme, this CP did not make any fundamental changes to how the extrusion molding process is performed and controlled.

Extrusion Molding Manufacturing Procedures

Written by Investigator Jerndal.

The principal document directing organizational control of procedures and practices for production and testing at this firm is the Bill of Operations (BOO). Examples can be seen in the batch extrusion process work orders, Exhibits R2 through R5. The current extruded part number [illegible] BOO Revision [illegible] dated [illegible] calls out the following procedures and documents, in order, describing and controlling extrusion molding processing.

Exhibit R7, Manufacturing Procedure [illegible] Revision [illegible] dated [illegible], "Manufacturing Line Clearance" - this document directs the clearing of a workstation or production line of materials, components, labels, and documents to ensure there is no cross-contamination between difference work orders.

Exhibit R8, Manufacturing Procedure [illegible], Revision [illegible] dated [illegible] "Extruder Equipment Setup" – this document describes the procedure for the extruder equipment setup including reference to part specific setup sheets for processing parameters to be used.

Exhibit R9, Form Specification [illegible], Revision [illegible], dated [illegible] "Extruder Run Sheet" – extruder run sheet for recording selected processing parameters.

Exhibit R10, [illegible] Revision [illegible], dated [illegible], "Work-Order Bill" – describes the process in which a work order is picked by staging and built by manufacturing using the [illegible]

Exhibit R11, [illegible] Revision dated [illegible] "Molding Material Handling" – this document provides an outline for material handling, including component mixing, i.e. resin and color concentrate.

Exhibit R12 [illegible], Revision [illegible] dated [illegible] "Material Dryer Cleaning & Startup" – this document describes the procedure for the [illegible] dryer cleaning and startup and cites the BOO as documenting the minimum time and temperature specification. It also directs recording of this information on the BOO for each batch.

Exhibit R13, [redacted] Revision [redacted] dated [redacted] "Extruder String-up & Production" – this procedure directs additional requirements for extruder setup and extrusion molding production. This procedure directs introduction of material to be extruded and establishing procedures to achieve process stabilization.

[redacted] describes specific adjustments that can be made to affect extruded product dimension. According to Mr. Shirley, the process adjustment latitude allowed is established within the plus or minus range documented on the extruder setup sheet for each part. For example, the extruder setup sheet for the part [redacted] attached as Exhibit R23. [redacted] directs deploying the [redacted] to be set up per the part's specific setup sheet parameter. This gauge monitors the outside diameter of the extruded product.

According to Mr. Shirley, if the laser micrometer alarm sounds, indicating a variation in the outside diameter of the extruded product, or if an examined sample is found out of tolerance, the operator may adjust the equipment to regain tolerance stability of the process. That adjustment, however, can only be made within the plus or minus tolerances established on the setup sheet, according to Mr. Shirley. The procedure itself does not explicitly state this, however. Should such an event occur, it would be recorded on the device history record attribute sheet. Mr. Shirley indicated that the equipment operator told him that such an event has not occurred (within his memory). I asked Mr. Shirley if they maintained any summations or trend data on extrusion molding product test result. Mr. Shirley said no, they had not, that the process is very stable and they maintain results of test data in each individual batch record; that there has been no need to trend this information as once the process is set up and stabilized, it runs smoothly without deviation. I noted no deviations or out of tolerance test samples for the four batches I reviewed during this inspection.

Exhibit R14, [redacted]

Exhibit R15, [redacted] – describes the procedure for printing labels for extrusion product batching boxes.

Exhibit R16, [redacted] Revision [redacted] dated [redacted] "Label Reconciliation and Verification" – instructions for reconciling and verifying labels printed for production.

Exhibit R17, [illegible] (Each of the other [illegible] parts produced by extrusion molding has its own assigned attribute inspection form.). This particular example for the part [illegible], references [illegible] (Exhibit R19) and directs a sampling interval of [illegible] and sample size of [illegible]

Exhibit R18 [illegible] Revision [illegible] dated [illegible] "Statistical Process Control Chart Procedure For Molding" – this is a generic procedure defining this firm's statistical process control (so-called) practices for molding both injection and extrusion. Note that in the case of extrusion molding this "SPC" is the product sample taken during the extrusion batch run, measured for dimensional tolerances.

Exhibit R19, [illegible] this document describes the inspection procedures and criteria to be used in the acceptance of the [illegible] product. Section [illegible] identifies the measuring tools to be used, Section [illegible] establishes that parts will be inspected per the documents listed on the Bill of Operations (BOO) and the part drawing. Section [illegible] directs that the dimensional measurements for sampled parts are to be done at [illegible] of the sampled part. Section [illegible] tables the inspection criteria and method of inspection.

Exhibit R20. [illegible] this is an example of an extruded part drawing, in this case, the part [illegible] Mr. Shirley supplied this drawing with the indicated hand-drawn lines illustrating the particular dimensions that are checked with the indicated instrument as listed on the drawing.

Procedure # [illegible] is a second label reconciliation procedure, was not collected.

Exhibit R21, [illegible], Revision [illegible] dated [illegible] "Extruder Equipment Cleaning and Shut Down" – this document describes the procedure for shutting down, purging and cleaning the extruder following a production batch run.

Procedure [illegible] describes moving extruded batch parts to inventory. This procedure was not collected.

Exhibit R22, [illegible], Revision [illegible] dated [illegible] "Final Product and Subassembly Release" – this general procedure defines criteria for final product and subassembly inspection and release, including release of sterile products to sterilization by Quality Assurance, release of sterile final product for distribution, and [illegible] concerning review of work order device history record packets review.

With the exception of the procedures that reference a specific part, for example, a part drawing or test specification setup sheet, these procedures are generic to all of the extruded parts produced.

Part Tubing,
Written by Investigator Jerndal.

Exhibit R23 is a copy of the extruder setup sheet Revision established under Change Proposal (CP) , dated (Exhibit R6). Exhibit R24 is a copy of an old extruder setup sheet start dated for part INTRAN Plus Tubing work order . According to Mr. Shirley, this was an early (perhaps the initial) production run for this part using the then new Mr. Shirley supplied this setup sheet after a number of requests I made to him concerning the firm's documentation supporting its current setup parameters for extrusion molding. Mr. Shirley supplied this example to demonstrate, as he said, that there have been few changes to extrusion molding setup parameters over the past years. This issue will be discussed further below.

Exhibit R25 is a copy of the Engineering Drawing Revision dated This is the same part drawing as Exhibit 20 without the hand drawn lines of the prior example. Exhibit R26 is a copy of this engineering drawing revision that Mr. Shirley presented to compare with the current revision Exhibit R27 is a copy of a blank Bill of Operations (BOO), the currently applicable Revision , dated Exhibit 28 is a copy of a part BOO, Revision, dated that Mr. Shirley supplied to me to compare against Exhibit R27 current version, stating this was supplied to demonstrate similarity of the process since that time in Exhibit R29 is the Material Specification Revision dated Exhibit R30 is the Material Specification Revision , dated ' Exhibits R29 & R30 are the two raw ingredients mixed and extruded to produce the Part ;

Part Tubing,
Written by Investigator Jerndal.

Comparable documents for the other extruded part, reviewed during this inspection, the part "Tubing, ', for the includes:

Exhibit R31, , Revision, Extruder Setup Sheet, established as a formerly controlled document under Change Proposal , dated

Exhibit R32, Engineering Drawing Revision dated

Exhibit R99, Bill of Operations (BOO) for Part [redacted] current Revision [redacted], dated [redacted]

Exhibit R33, Material Specification [redacted] Revision [redacted] dated [redacted]' Exhibit R34, Material Specification [redacted], Revision [redacted] dated [redacted] (Exhibits R33 & R34 are the [redacted] materials [redacted]

Exhibit R35 is a Change Proposal [redacted] late submitted, [redacted], date released [redacted] This change proposal introduced changes to the extruder setup sheet [redacted] (Exhibit R31) for this part, [redacted]

Part [redacted]
Written by Investigator Jerndal.

The above [redacted] sets of documents cover the specifications for process control and raw materials for the [redacted] parts covered specifically during this inspection. The other [redacted] parts extruded [redacted] currently, include [redacted]

INTRAN PLUS Assembly and Work Order Review
Written by Investigator Jerndal.

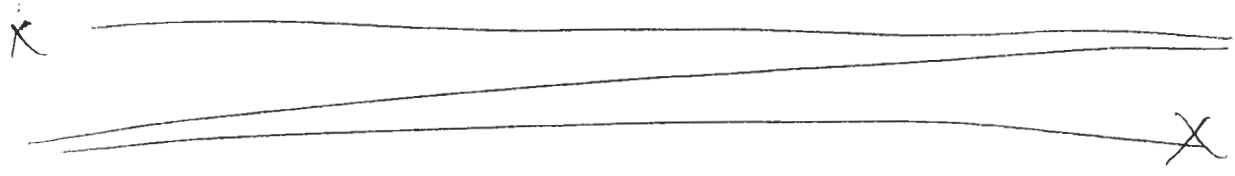
Exhibit R38 is a list of work orders completed since [redacted] up through [redacted], for the INTRAN Plus IUP Device Final Assembly. Each of the work orders are batch sizes of from [redacted] devices. I selected an approximate 10% sampling requesting all work orders ending in the number [redacted] The Part [redacted] is used for this assembly. That part is the primary catheter body. This tubing has two inner lumens, one large, one small; the large lumen contains the [redacted] for this catheter. The smaller lumen is used for, "The administration of oxytocin for the inducing or augmenting of contractions and aminoinfusion to help ensure adequate maternal-fetal circulation or dilation of meconium staining..." according to the (Exhibit L11) product brochure.

This part undergoes further processing. Manufacturing Procedure , Revision dated , Exhibit R39, describes and directs the process of for access to the small lumen. These ; with the other components in the assembly. Next, as directed under the Bill of Operations for this assembly, per the manufacturing procedure , Revision dated Exhibit R40. This is directed by Exhibit R41, Manufacturing Procedure , Revision , dated 8/8/02,

Of the work orders I reviewed, , work order , dated revealed units failed the testing (Exhibit R41). Otherwise, for the other work orders reviewed, the typical total failed ranged from units out of units tested, with batches showing units failed There was no notation as to the nature of the unit failures for the above work order. Mr. Shirley responded that the engineer responsible for this project informed him that the failures were at the catheter operation; that this catheter testing is designed in part to evaluate the operation as an result in violating the catheter interior wall. In this case, the operation was over and units failed testing.

Another issue noticed during my review of these work orders was that of scrap accountability. work orders reviewed revealed from to units unaccounted for in the final tally of devices produced for the respective batches. Batch numbers and numbers unaccounted for are as follows:

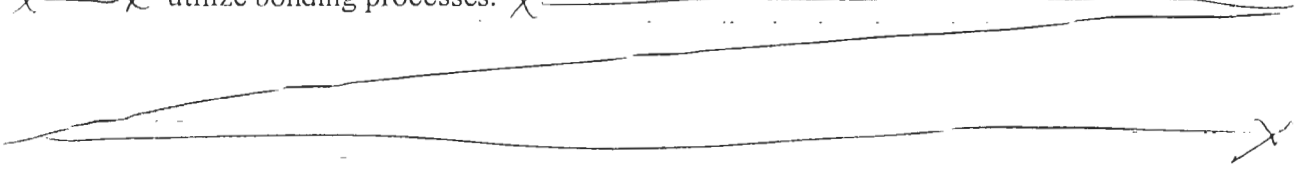
The number of units accounted for in any particular batch record occurs at a variety of places throughout the assembly as discerned by comparing the total number accepted at the various points in the Bill of Operations where that information is recorded. In none of these cases is there a notation as to the reason for the unaccountability or scraping, nor are there any related deviations applied to any of these work orders. I brought this to Mr. Shirley's attention. Mr. Shirley stated that they perform X—X trend analyses of percent yields on the INTRAN processing that is reported in the X——X That report notes percent yield for the final electrical test specifically, and percent yield for all other causes prior to the final electrical testing combined. The above tabled list of units accounted for this second category of otherwise unspecified scrap rate. Mr. Shirley stated that an engineer is assigned for this product line and is responsible for overseeing this assembly process, including review and control of yield issues. Mr. Shirley also stated that the MRB reviews percent yields for this product line and feels that the percent yields are quite low. Mr. Shirley stated that he felt there was no requirement in the GMP to otherwise document or specify in the Device History Record the reason for specific scrap at this low rate. I informed Mr. Shirley that to assign cause or location for the scrap offered the opportunity to extract additional information about this process that the firm may find useful for process improvement. Examples of the X—X report, reporting percent yields for the INTRAN product line can be found in the Exhibits as follows: Exhibit M10, Page 14; Exhibit M11, Page 15; Exhibit M12, Page 17; and Exhibit M5, Page 18. X—X examples of INTRAN Plus work orders from the above table are exhibited here as follows.



BONDING PROCESSES

Written by Investigator Jerndal.

Assembly operations for X of this firm's primary product lines, the X——X illustrated in the product brochure X—X and the X——X X——X illustrated in product brochure X—X utilize bonding processes. X——X



operations were reviewed during this inspection, chosen for their connection to corrective action requests, and as follow-up to bonding processes reviewed during the previous inspection. Also bonding was chosen for review that represent a variety of bonding types.

CAR [redacted] and [redacted]

From a list of all corrective action requests occurring between [redacted] to the present, [redacted] CARS were requested for review that involved a field complaint as follows, CAR [redacted] On Wednesday, 2/04, I reviewed CAR [redacted] originator/date [redacted] The Corrective Action document presented for review at this time is included here as Exhibit R51. This Corrective Action was initiated in response to a customer complaint concerning [redacted] which was reported to have leaked at the tubing bond of tubing part [redacted] and female connector [redacted] Of [redacted] units returned by this customer, [redacted] of the used units and [redacted] of the unused units were [redacted] A copy of that complaint [redacted] received on [redacted], is attached as Exhibit R52. I requested information on the current status of this corrective action. On 2/07, Saturday, Ben Shirley supplied an updated version of this Corrective Action [redacted]. This updated [redacted] is submitted here as Exhibit R53. This remains an open corrective action. The Exhibit R53, [redacted] Correction of Immediate Nonconformance states, [redacted] This CAR documentation is silent on the impact on forward production. The CAR root cause analysis concludes, [redacted] The Corrective Action Plan is stated as, [redacted]

Exhibit L66 is the specification for the female connector [redacted] Exhibit R54 is a copy of the Material Specification [redacted] Revision [redacted] dated [redacted] The bond in question is illustrated, for example, on the [redacted] Engineering Drawing portion of Exhibit R88, with the note, [redacted] Manufacturing Procedure [redacted], Revision [redacted], dated [redacted] Assembly, is attached as Exhibit R55. [redacted] Each part is visually inspected by the assembler. The procedure Exhibit R55 lists the visual defects to inspect for.

In addition, each [redacted] per the Manufacturing Procedure [redacted] Revision [redacted] dated [redacted], submitted here as Exhibit R56. This is [redacted] testing.

OBJECTIONABLE CONDITIONS

On 3/3/04, a FDA-483, Inspectional Observations, was issued to Kevin L. Cornwell, CEO/Chairman, in the presence of Mr. Shirley. Mr. Cornwell also had individuals connected via telephone as follows: Larry Pilot, Attorney; Dan Jarcho, Attorney; and [redacted] FDA Investigators Medina, Wilkins, and Jerndal were also present.

The close-out meeting was audio taped in its entirety and the tapes are included as Exhibits L1. The tapes are contained with the original EIR only. Mr. Cornwell stated that he did not wish to have the FDA-483 annotated and he did not promise to correct the observations made on the FDA-483. The Investigator responsible for each observation has provided the supporting text and documentation and the author of each item is noted.

Observations listed on form FDA 483

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures.

For example,

a) **Extrusion molding processing parameter operation control limits (i.e. heating zone, die, adaptor and clamp/gate temperatures, variac setting, screw RPM, head pressure, puller and cutter speed, and laser micrometer setting) are not supported by an examination of their relationship to the true control limits (edge of failure).**

b) **Injection molding processing tolerance limits (temperatures, pressure, speed, injection time) have not been challenged, there is no documentation to support that test sampling plan was based upon a statistically valid rationale [redacted] and there is no documentation to support that process equipment [redacted] was properly installed. Validation activities have not been conducted on the [redacted] programmable logic control system utilized to establish actual operating parameters of the injection molding equipment. This was observed for injection molded part [redacted]**

c) **The material drying process has not been qualified or validated. The drying process includes a [redacted] hour dry time at a temperature of [redacted] degrees Fahrenheit (BOO Process Number [redacted] Operation [redacted]. Work order number [redacted] dated [redacted] documented that [redacted] material was dried at [redacted] and [redacted] degrees Fahrenheit between [redacted] Work order number [redacted] dated [redacted] documented that [redacted] material was dried between [redacted] and [redacted] degrees**

Fahrenheit between [redacted] The material [redacted] specification sheet states [redacted] work orders (a total of [redacted] documented runs) were reviewed between [redacted] for injection molded part [redacted]

d) The annealing process qualification associated with injection molded part [redacted] is not complete in that data/documentation does not exist associated with [redacted] for the operations as follows: [redacted] the test. The current Bill of Operations (Process No. [redacted] Operation [redacted] states to anneal parts [redacted]) to procedure [redacted] Manufacturing procedure [redacted] entitled "HEAT ANNEALING PROCEDURE", Rev. [redacted], dated [redacted] (section [redacted], states to preheat oven to [redacted] degrees Fahrenheit [redacted] and place trays in preheated oven for [redacted] minutes (section [redacted].

Additionally, this same test report documents qualification for the [redacted] bonding process used to assemble PVC tubing to [redacted] connectors in the Deltran assembly. The raw data supporting this summary report was not retained.

e) Bond qualification for the [redacted] revision [redacted] adhesive was last done on [redacted] as part of [redacted] Bond qualification for the [redacted] rev. [redacted], dated [redacted] was last done [redacted] as part of [redacted] revision [redacted]. The firm was unable to provide data to demonstrate that these [redacted] bond process qualifications support the current process.

f) There is no maximum time established for pre-extrusion drying of the [redacted] used to mold the Assembly [redacted]

Reference: 21 CFR 820.75(a)

PURGED

Relevance/Additional details of the observation:

FDA-483 ITEM NUMBER 1a: Written by Investigator Jerndal.

At the end of the day, Tuesday, 2/10/04, I asked Ben Shirley if Utah Medical had done a validation supporting the setup parameters for their extrusion molding process since the last inspection. He replied that they had not. I asked if they had any prior validation for the process. He said yes, but that it was old and would be difficult to find. I requested any validation work that they might have supporting this process. On Wednesday, 2/11/04, I again reminded Mr. Shirley of my request for any validation or qualification that the firm may have that supports the current extrusion molding setup parameters. On Thursday, 2/12/04, Ben Shirley gave me two documents he indicated were related to an extrusion process qualification as follows:

- Exhibit R45 is a copy of test protocol
- Exhibit R46 is a copy of test report Revision , dated

These documents were presented without any explanation other than that they supported the extrusion process qualification. A review of these documents revealed that they involved work done in to evaluate INTRAN Plus Tubing (Part Replacement Material. As their then current production material, was no longer (then) available. The Exhibit R45 Test Protocol lists the materials evaluated (one being the material). Ultimately, number from that list, namely, was selected for new production remains the current resin material used for this part (Exhibits R29 and R30). Exhibit R46 pages and describe the various test report summaries attached to this final report Neither of these documents describe the production setup parameters used to produce the samples manufactured for testing described in this protocol and test report. The notation on Exhibit R45 indicates that pieces, lot #42674 were manufactured for this evaluation. I requested the Device History Record for this lot, and was later told by Mr. Shirley that they no longer had this documentation.

On Thursday, 2/12/04, at the end of the day summary, I informed Mr. Cornwell, Mr. Shirley and that extrusion molding process parameters remain unsupported by validation and that this would be a continuing citation for the outcome of this inspection. Following this, at this meeting, Mr. Cornwell announced that he was now ready to respond to the findings of the previous inspection and to issues brought to their attention, including the extrusion molding validation issue discussed at this meeting. At this time, the inspection plan was to break from the inspection that evening, Thursday, 2/12/04, and reconvene Tuesday, 2/17/04.

Ultimately, the break in the inspection was extended through Sunday, 2/22/04, and we reconvened Monday, 2/23/04. To begin that day, Mr. Cornwell held a taped meeting where he introduced and supplied us with a copy of a spiral binder, Exhibit L10, indicating that it was documentation of

where the firm was currently for each of the previous 483 items. "Our best foot forward" stated Ben Shirley. We indicated that we would review this material as part of our ongoing inspection. Sections 1D of this binder (corresponds with observation 1D from the previous inspection 483) addresses the findings of the past inspection that there was no approved extrusion process validation. The firm's position, as summarized in the 2/19/2004 memo to that section, is that this is XXX equipment in long term and extensive use. They state their opinion that XXXXX units shipped with no complaints or evidence of failures by itself validates the X ——— X ; with a high degree of assurance.

Later in the day on Monday, 2/23/04, XXXXXY gave me a large stack of XX documents he said was related to extrusion molding. A review of this material revealed it to be comprised of a variety of extrusion molding equipment manuals and miscellaneous older drawings, documents, extruder die drawings, and some documents describing the initial purchase and installation, and employee training that occurred around X ——— X when the extrusion molding equipment was first purchased and installed at Utah Medical.

One of the documents in this miscellaneous material - Exhibit R47 is a copy of a memo dated , subject: 'X ——— X ' that describes title and contents of a variety of documents, miscellaneous materials, related to extrusion molding and its equipment and its storage locations. None of this material appears to document specific processing parameters utilized during this early period nor does it appear to connect to any underlying validation of process setup parameters for extrusion molding.

On Tuesday, 2/24/04, I discussed the Exhibits R45 and R46, XV INTRAN Plus Tubing Materials Evaluation with Mr. Shirley. I told him that, without documented connection of this 'YXX report to current conditions and practices for extrusion molding of this XXXX this represents work lost due to a failure to maintain documentation continuity, or is the basis for misplaced confidence in a process that may have drifted away from conditions in place during this XX qualification. I discussed with Mr. Shirley that for this early work to continue to be useful, documentation showing linkage to this early work should be up to date and presentable and updated; that it appears not to be is itself problematic. However, if they were able to demonstrate continuity and present a documented rationale for supporting current operations with this work noted in XXX, I advised them to produce it and I would review it in the context of the extrusion molding review.

On Wednesday, 2/25/04, Mr. Cornwell held a taped morning meeting (we had no end of day summary at the end of the prior day). Investigator Medina again requested any information that might document that the injection molding process is operating under control, including any validation work establishing process control parameters. We were informed that Utah Medical has submitted substantial quality information to a contract "expert in molding processes" to evaluate the status of molding processes, and to make any recommendations to improve the ongoing support for molding processes. As to the extrusion molding process, we were told that a "retrospective validation" was under consideration as part of this involvement with this consultant. They declined

to tell us who the consultant was and stated only that it is a review of historical data that has not yet been submitted or written into any final form or report. I asked if they had submitted to the consultant any quality system information relating to molding that we have not yet been provided as our review is in the same area. Their response was ambiguous stating that it was historical data but intimating that there may be more information. I asked if they had done or were doing any additional engineering work to support this effort. Again, their response was similarly ambiguous.

Later Wednesday morning, 2/25/04, Ben Shirley supplied me with three Engineering Change Requests that he stated would demonstrate the linkage between the [redacted] Test Report (Exhibit R46) and extrusion molding current operating conditions. These are exhibited here as follows:

Exhibit R48, Engineering Change Request C/R [redacted] date implemented [redacted] – this documentation contains qualification work done of new printing ink that is applied to the catheter body.

Exhibit R49, Engineering Change Request C/R [redacted] date implemented [redacted] – this document introduces dimensional changes to the [redacted] part number for extrusion tubing, [redacted] of this exhibit under section entitled Recommendations, states, [redacted]

Page [redacted] of this exhibit, a memo from [redacted] the last two sentences of the first paragraph state, [redacted] Beginning second paragraph, [redacted] It is not clear from this documentation how circumstances described in this change request impacted process and product parameters then nor does it appear to demonstrate linkage to the current process and parameters as alluded to by Mr. Shirley.

Exhibit R50, Engineering Change Request C/R [redacted] date implemented [redacted] updates the Bill of Materials and Bill of Operations with [redacted]

No additional documentation is attached or referenced.

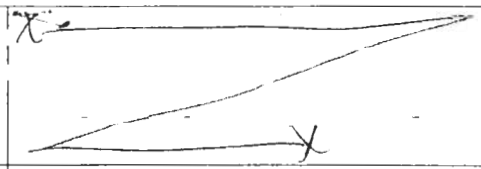
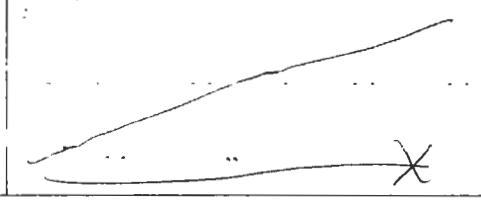
At the end of the day, Wednesday, 2/25/04, Mr. Shirley supplied me with a copy of an old Extruder Setup Sheet for Work Order , Part dated , attached as Exhibit R24. Mr. Shirley stated that the lot #42674 Build of Samples noted on page of Exhibit R45 , dated was no longer available and that this setup sheet was an example from that time period illustrating the setup parameters the firm used with this then new material, the same material in current use today, for extrusion molding of Part tubing.

In the morning of Wednesday, 2/25/04, Mr. Shirley also supplied me with printouts of the Bill of Operations current Revision level and the Revision level version dated These two documents are attached as Exhibits R27 and R28 respectively. Mr. Shirley indicated these were supplied for comparison to show similarity in the process between conditions during the introduction of new material circa and current operating conditions. I asked Mr. Shirley if Utah Medical had ever done any study or review of the effects of various extrusion process parameter changes on the extrusion product. He said he thought they had but, "it would be difficult to find that old stuff, but he'd check." No additional information or documentation of this nature was supplied by the conclusion of this inspection. No documentation was presented to support set-up parameter validation for the other three parts produced by extrusion molding.

FDA-483 ITEM NUMBER 1b: Written by Investigator Medina.

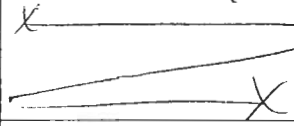
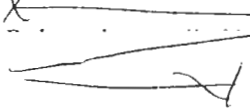
Injection molding processing tolerance limits (temperatures, pressure, speed, injection time) have not been challenged. The lack of validation for injection molding is a repeat observation noted on the previous FDA 483's for 2003 and 2001. Ben Shirley, Quality Manager, provided information associated with the injection molding equipment set-up as follows:

EXHIBIT	DOCUMENT	DESCRIPTION
L17	"MOLDING SET-UP SHEET" for machine number	This is a representative example of an injection molding operational set-up sheet which includes processing equipment parameters.
L18	FORM SPECIFICATION number ; RUN SHEET-MOLDING; Revision dated	The "RUN SHEET" documents the processing information (but not limited to) as follows:

		
L19	TRAINING DOCUMENT number [redacted] entitled "INJECTION MOLDING PROCESS SET-UP AND PRODUCING PART", Revision [redacted] dated [redacted]	Contains injection molding process set-up instructions [redacted] producing parts [redacted] and completing injection molding work orders [redacted] Section [redacted] states to [redacted] Section [redacted] states [redacted] 

No data exists to support operational or performance qualification activities associated with injection molding equipment as it is present at the firm.

There is no documentation to support that test sampling plan was based upon a statistically valid rationale [redacted] Ben Shirley, Quality Manager, provided information associated with the injection molding part sampling and testing as follows:

EXHIBIT	DOCUMENT	DESCRIPTION
L20	"Control Chart for Variables" for Part number [redacted] entitled [redacted] 	Contains control limits for Mean and Range (LCL and UCL). Additionally, a sampling plan is specified for a sampling interval of [redacted] hours and a sample size of [redacted]
L21	"Attribute Inspection Form" for Part number [redacted] entitled [redacted] , 	Contains visual inspection defect descriptions for flash, incorrect luer taper, short shot, and others. Additionally, a sampling plan is specified for a sampling interval of [redacted] hours and a sample size of [redacted]

Mr. Shirley stated that the firm's sampling plan associated with all injection molded parts manufactured at the firm is similar as mentioned above [redacted] See also the discussion of the firm's use of SPC (measuring product characteristics) found within FDA-483 item number 2a and the Objectionable Conditions section of this report.

During this inspection, physical sample testing [redacted] was observed (work

order number [illegible] Exhibit L22) in which the inner diameter of the [illegible] was tested via use of a pin gauge on 2/23/04. The pin gauges are marked with sizes [illegible] (see discussion below). These measurements are recorded on the "Control Chart for Variables" for Part number [illegible] entitled [illegible]

Pin gauges were observed to include [illegible] sizes as follows: [illegible] The inspector stated that she would record [illegible] on the "Control Chart for Variables" when the [illegible] gauge fit "snuggly" within the [illegible] and when the [illegible] gauge would not go to the bottom of the [illegible]. The actual data recorded on the "Control Chart for Variables" sheet is directly associated to the inspectors touch/feel and experience in testing the component.

The above mentioned part is manufactured into the Deltran device line and is subjected to a [illegible] operation (see FDA-483 item number 1d and the Objectionable Conditions section of this report which discusses part qualification). The part is measured for this dimension ([illegible]) prior to acceptance into manufacturing of the finished device. If this part is too small or too large there is a possibility that the [illegible] will not process correctly due to the improper fit/incorrect part size.

Three (3) work orders were reviewed during this inspection for injection molded parts manufactured between [illegible] A summary of these work orders is as follows:

WORK ORDER [illegible] (Exhibit L23):
Exhibit L23 contains documentation associated with the manufacturing of this work order of injection molded parts [illegible] Documentation is as follows:

EXHIBIT/PAGE(S)	DOCUMENT DESCRIPTION
L23/1-3	WORK ORDER TRAVELER
L23/4	RUN SHEET
L23/5	MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured)
L23/6-42	Control Chart for Variables and Attribute Inspection Forms for processing which occurred between

Mr. Shirley stated that this work order contained the parts manufacturing and testing which aided in the establishment of the firm's SPC.

WORK ORDER [illegible] (Exhibit L24):
Exhibit L24 contains documentation associated with the manufacturing of this work order of injection molded parts [illegible] Documentation is as follows:

EXHIBIT/PAGE(S)	DOCUMENT DESCRIPTION

L24/1-3	WORK ORDER TRAVELER
L24/4	RUN SHEET
L24/5-6	MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page X MOLDING SET-UP SHEET (established set-up specifications) – Page X
L24/7-38	Control Chart for Variables and Attribute Inspection Forms for processing which occurred between

WORK ORDER X ——— X (Exhibit L25):

Exhibit L25 contains documentation associated with the manufacturing of this work order of injection molded parts X ——— X Documentation is as follows:

EXHIBIT/PAGE(S)	DOCUMENT DESCRIPTION
L25/1-3	WORK ORDER TRAVELER (copy unreadable except for part label and total quantity; best possible copy obtained)
L25/4	RUN SHEET
L25/5-6	MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page X MOLDING SET-UP SHEET (established set-up specifications) – Page
L25/7-28	Control Chart for Variables and Attribute Inspection Forms for processing which occurred between X ——— X IN-PROCESS MOLD MAINTENANCE (Page

A summary of the total number of parts X ——— X produced and the number of physical samples tested in each work order is as follows:

EXHIBIT/PAGE	WORK ORDER	TOTAL NUMBER OF PARTS	NUMBER OF SAMPLES TAKEN(*)
L23/1	X ——— X		
L24/1	X ——— X		
L25/1	X ——— X		

(*) "Control Chart for Variables" for Part number XXX entitled X ——— X X ——— X which contains control limits for Mean and Range (LCL and UCL); sampling plan is specified for a sampling interval of X — X and a sample size of X ——— X

There is no documentation to support that process equipment X ——— X was properly installed. Ben Shirley, Quality Manager, provided an instruction manual for the X ——— X X ——— X Several pages from this manual are found as Exhibit L26 which includes the information as follows: system requirements for injection unit, clamping

unit, and others (heater capacity, pump motor, oil tank capacity, etc.); auto zero adjustment; and regular checking (daily, weekly, and monthly) and trouble shooting. This is a representative example of pages contained within this user manual.

Validation activities have not been conducted on the X ——— X utilized to establish actual operating parameters of the injection molding equipment. Mr. Shirley stated that the firm has not conducted validation or qualification activities associated with other programmable logic control systems associated with actual operating parameters of injection molding equipment currently present at the firm.

Ben Shirley, Quality Manager, stated that this system "remembers" or maintains the injection molding set-up parameters in between processing days (when processing occurs over several days). The operators do not need to re-enter the injection molding set-up parameters from one operational day to the next. Only one actual processing parameter document (entitled "MOLDING PARAMETER CHART") is found within the work order packet for manufactured parts. The chart documents the actual processing parameters that the injection molding equipment is operating under. The operators do not print off a "MOLDING PARAMETER CHART" for each new process run. Mr. Shirley stated that the operators only print off a "MOLDING PARAMETER CHART" after the initial set up to document that the actual injection molding equipment is operating per the established "MOLDING SET UP SHEET" (example found as Exhibit L17). I stated that the operators should verify that the operational set-up parameters continue to be the approved set-up for the molded part. Mr. Shirley agreed; however, he stated that the computer system "remembers" the processing set-up from one run to the next. I stated that there is no documentation to support this statement.

Mr. Shirley provided an instruction manual for the X ——— X X ——— Several pages from this manual are found as Exhibit L27 which includes the information as follows: (table of) contents; operation panel (Pages 3-4); mold mounting and clamping force setting (Pages 5-6); setting of mold and ejector movements (Pages 7-9); injection setting stage (Page 9); charging setting stage (Page 10); test molding stage (Page 10); explanation on screens (Pages 11-12); mold movement (Page 13); injection (Page 14); and monitoring (Page 15). This is a representative example of pages contained within this user manual.

Several documents were collected in association with the firm's injection molding operations. A summary of these documents is as follows:

EXHIBIT/PAGES	INJECTION MOLDING DOCUMENT
L28/1-2	Utah Medical Molding Machines, Materials, Equipment, Information Sheet dated X ——— X which includes a listing of the X ——— X molding machines which are present at the firm.
L28/3-9	A listing of injection molded parts (via part numbers); a description of the part; the mold number; and the

	machine(s) on which the part is manufactured.
L29/1-4	In-house molded parts dated X—X via part number and part description.
L29/5-6	Indented Bill of Material for Deltran IV X—X and IUP-400 Intran Plus X—X devices dated X—X part number and description.
L30	MANUFACTURING PROCEDURE number X—X entitled "MANUFACTURING LINE CLEARANCE"; Revision X, dated X—X
L31	QUALITY ASSURANCE PROCEDURE number X—X X entitled "FIRST ARTICLE INSPECTION"; Revision X dated X—X
L32	QUALITY ASSURANCE PROCEDURE number X—X X entitled "INJECTION MOLDED PARTS"; Revision X undated
L33	TRAINING DOCUMENT number X—X entitled "MOLDING EQUIPMENT START-UP AND SHUT-DOWN PROCEDURES"; Revision X, dated X—X
L34	TRAINING DOCUMENT number X—X entitled "MOLDING MATERIAL HANDLING"; Revision X dated X—X
L35	TRAINING DOCUMENT number X—X entitled "REGRIND PROCEDURES"; Revision X, dated X—X
L36	TRAINING DOCUMENT number X—X entitled "INJECTION MOLD INSTALLATION AND REMOVAL"; Revision X, dated X—X
L37	TRAINING DOCUMENT number X—X entitled "MOLDING DEPARTMENT MOLDED PART HANDLING"; Revision X, dated X—X

Several nonconformances associated with injection molded parts were noted during the course of this inspection and a summary of these documents is as follows:

EXHIBIT/PAGES	INJECTION MOLDING NONCONFORMANCE DOCUMENT
L38	REQUEST FOR DEVIATION/WAIVER dated X—X; number X—X for X—X ~~~) associated with laser mike calibration due. This part is manufactured into the Deltran device line.
L39	REQUEST FOR DEVIATION/WAIVER dated X—X number X—X for P/N X—X

	connector) associated with the [redacted] This part is manufactured into the Deltran device line.
L40	REQUEST FOR DEVIATION/WAIVER dated [redacted] number [redacted] for P/N [redacted] associated with the [redacted] This part is manufactured into the Deltran device line.
L41	RETURN GOODS AUTHORIZATION number [redacted] dated [redacted]. Part number [redacted] (resisting element) "failed testing" and was scrapped. This part is manufactured into the Deltran device line. No failure investigation/root cause analysis upon the "failed testing" was conducted prior to this lot of injection molded parts being scrapped.
L42	Nonconforming Material Report number [redacted] dated [redacted] associated with P/N [redacted] (stopcock assembly) having [redacted]
L43	Nonconforming Material Report number [redacted] dated [redacted] associated with P/N [redacted] having [redacted] rework.
L44	Nonconforming Material Report number [redacted] dated [redacted] associated with P/N [redacted] (tubing, connector, female) being [redacted] The UCL and LCL will be [redacted] See FDA-483 item number 2a and the Objectionable Conditions section of this report.

The management of the firm was informed on 3/1/04, at which time my review of the injection molding operations and associated procedures/documents had been concluded, that injection molding validation (processing tolerance limits, sampling plan, installation of processing equipment, material drying process, annealing process, etc.) would be cited as an observation on the FDA-483, Inspectional Observations.

FDA-483 ITEM NUMBER 1c: Written by Investigator Medina.

The [redacted] material (used in injection molded parts manufacturing) drying process has not been qualified or validated. This drying process includes a [redacted] hour dry time at a temperature of [redacted] Fahrenheit (BOO Process Number [redacted], Operation [redacted] which is found as Exhibit L45). The actual instructions, as found on the BOO, state [redacted]

The material [redacted] specification sheet is found as Exhibit L46 and is entitled [redacted] Page [redacted] states [redacted] Ben Shirley, Quality Manager, stated that the firm has not conducted a qualification upon this material and no additional drying information is contained within a design history file. This material specification sheet is the guide by which the firm processes the material utilized in the injection molding equipment. Exhibit L47 is a representative example of additional specification information associated with this material. Page additionally states [redacted]

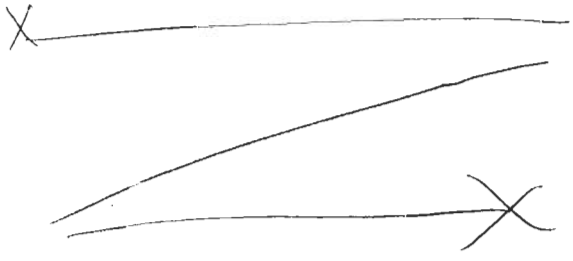
Exhibit L48 is a representative example of the dehumidifying dryer [redacted] that the firm utilizes to dry the material which contains unit specifications, preparation for operation, and maintenance and inspection.

Exhibit L49 is a TRAINING DOCUMENT entitled "MATERIAL DRYER CLEANING AND START UP", [redacted], Revision [redacted] dated [redacted]. Page [redacted], Section [redacted] states [redacted]

Work order number [redacted] dated [redacted] documented that [redacted] was dried at [redacted] and [redacted] degrees Fahrenheit between [redacted] Exhibit L23, Page [redacted] is the "RUN SHEET" for work order number [redacted] which documents the "Material Dryer (temperature and dew point). A summary of the dryer time associated with this work order is as follows:

[redacted]

Work order number [redacted] dated [redacted] documented that [redacted] was dried between [redacted] and [redacted] degrees Fahrenheit between [redacted] Exhibit L25, Page [redacted] is the "RUN SHEET" for work order number [redacted] which documents the "Material Dryer (temperature and dew point). A summary of the dryer time associated with this work order is as follows:



work orders [redacted] documented runs) were reviewed between
for injection molded part ([redacted]

Mr. Shirley stated that the operators typically only record one drying temperature on the Run Sheet for the entire run which is typically the first run of injection molded parts. The drying temperature is not routinely monitored during the operational running of the injection molding equipment. Mr. Shirley stated that the material needs to be dried in between runs and prior to the material being utilized during injection molding operations. This drying in-between runs is not documented on the Run Sheet.

The management of the firm was informed on 3/1/04, at which time my review of the injection molding operations and associated procedures/documents had been concluded, that injection molding validation (processing tolerance limits, sampling plan, installation of processing equipment, material drying process, annealing process, etc.) would be cited as an observation on the FDA-483, Inspectional Observations.

FDA-483 ITEM NUMBER 1d: Written by Investigator Medina.

Exhibit L50 is a document entitled [redacted] This document addresses [redacted] There is no documentation/data to support a validation associated with the annealing process.

Exhibit L51 is "TEST PROTOCOL - [illegible] QUALIFICATION, P/N [illegible], document number [illegible], Revision [illegible] dated [illegible]. Exhibit L52 is [illegible] (Annealing Process) document number [illegible] - [illegible] Revision [illegible] dated [illegible]

Data does not exist to demonstrate that activities as specified within the protocol were conducted for the operations as follows: part annealing; environmental cycle; accelerated aging; the number of parts that were [illegible] sterilized; the number of parts that were bonded and pull tested; and the date and name of the individual performing the test. A description of these activities as found within the protocol is as follows:

TEST PROTOCOL OPERATION NUMBER/ EXHIBIT INFORMATION	DESCRIPTION OF EVENT
6.2 (Exhibit L51, Page 3)	Annealing: Anneal P/N [illegible] per [illegible], Heat Annealing Procedure using a temperature of [illegible] (Exhibit L64)
6.3 (Exhibit L51, Page 3)	Bonding: Bond [illegible] tubing to the P/N [illegible] s using [illegible] adhesive on an equal number of [illegible]
6.4 (Exhibit L51, Page 3)	Bond Strength: Test and record the bond strength for all [illegible] bonding materials prior to [illegible] sterilization.
6.5 (Exhibit L51, Page 3)	[illegible] Sterilization: Send c [illegible] assemblies bonded with all [illegible] materials out for [illegible] cycles of [illegible] sterilization. Include bare P/N [illegible] 3 [illegible] assemblies. Check connectors and assemblies after each cycle [illegible] or other defects resulting from the [illegible]
6.7 (Exhibit L51, Page 4)	Temperature Cycling: Place the parts and assemblies tested in 6.5 in the environmental chamber and cycle the temperature between [illegible] for [illegible] days. Check [illegible] and other defects resulting from the temperature cycling.
6.8 (Exhibit L51, Page 4)	Accelerated Aging: Place the parts and assemblies tested in 6.7 in a temperature chamber for accelerated aging. To

	simulate a year aging process, the parts are held at a temperature of ——. Check and assemblies after aging for or other defects resulting from the temperature aging process.

Additionally, data does not exist to demonstrate that activities as specified within the test report were conducted for the operations as mentioned above. A description of these activities as found within the test report (Exhibit L52, Page 2, Section 3.0 entitled "QUALIFICATION TESTS") is as follows:

TEST REPORT OPERATION NUMBER	DESCRIPTION OF EVENT
3.1 (relatable to protocol section 6.2)	The annealing process was done per . The group of parts tested had different molding parameters. Each group was checked before and after the annealing process. No were visible through the use of a microscope.
3.2 (relatable to protocol section 6.3)	The parts were then bonded with per —— The with different adhesives ——. No were visible after this process as well.
3.3 (relatable to protocol section 6.4)	Pull tests were performed on units prior to (Test results found on Pages
3.4 (relatable to protocol section 6.5)	exposures were completed on all units. No sign of ; were found.
3.6 (relatable to protocol section 6.7)	Seven day environmental cycle was completed. No sign of ; were found.
3.7 (relatable to protocol section 6.8)	year accelerated aging is in process and will be completed on —— The results will be added to the Test Report. (Accelerated aging test completed —— results, no were found on any of the three groups identified in sec. 3.2 on this test report.)

Ben Shirley, Quality Manager, provided Exhibit L53 as documented evidence that the parts were injection molded for this protocol under "EXTRA PROCESS WORK ORDER (EPWO)" for old lot number —— new lot number dated Mr. Shirley stated that these parts were molded for even though this document does not state this. I stated that these parts

were molded prior to the approval of the "TEST QUALIFICATION, P/N ", document number Revision dated

Mr. Shirley stated that these parts were injection molded under "controlled production conditions" as specified on the EPWO section entitled "INSTRUCTIONS FOR PROCESSING". The mold heater temperature and temperature controller parameters respectively) varied. The exact number of parts which were run under the above mentioned conditions could not be determined from the information contained within this work order manufactured on

Exhibit L54, Page is the Bill of Materials - BOM (Procedure: dated for part number Exhibit L54, Pages is the Bill of Operations – BOO (Procedure: dated for part number Mr. Shirley stated that this is the BOM and BOO associated with the processing of the above mentioned parts in association with "TEST PROTOCOL ", document number , Revision dated There is no documentation or data to support that the annealing process was conducted per The test report states that the There were processing parameters and it is not specified the number of parts that were processed under each parameter nor the number of parts which were tested for e and after the annealing process.

There is no documentation that the parts were then bonded with , per . The tubing was bonded with – different adhesives The test results (without supporting documentation) is found as Exhibit L52, Pages

exposures were documented as being completed on the experimental units processed under "EXTRA PROCESS WORK ORDER (EPWO)" for old lot number dated . A summary of these cycles is as follows:

PROCESS/RETORT NUMBER dated

Exhibit L55 is a SUBMISSION FORM (Process/Retort number) dated which specifies that is to be sterilized. Ben Shirley, Quality Manager, stated that this "test box" contains the injected molded parts which are part of the "TEST PROTOCOL P/N , document number , Revision dated I stated that there is no clear delineation between the molded parts which are contained within this study and these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L56 is the (lab completion date

[redacted]). Page [redacted] indicates that this laboratory number [redacted] identifies the sample taken from process number [redacted]. This documents the sterility of this batch of parts.

[redacted] PROCESS/RETORT NUMBER [redacted] dated [redacted]

Exhibit L57 is a SUBMISSION FORM (Process/Retort number [redacted]) dated [redacted] which specifies that [redacted]' is to be sterilized. Ben Shirley, Quality Manager, again stated that this "test box" contains the [redacted] molded parts which are part of the "TEST PROTOCOL - [redacted] QUALIFICATION, P/N [redacted], document number [redacted], Revision [redacted], dated [redacted]. I stated that there is no clear delineation between the [redacted] molded parts which are contained within this study and these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L58 is the "[redacted]

[redacted]. Page [redacted] indicates that this laboratory number [redacted] identifies the sample taken from process number [redacted] This documents the sterility of this batch of parts.

[redacted] PROCESS/RETORT NUMBER [redacted] dated [redacted]

Exhibit L59 is a SUBMISSION FORM (Process/Retort number [redacted]) dated [redacted] which specifies that [redacted] is to be sterilized. Ben Shirley, Quality Manager, stated that this "test box" contains the [redacted] molded parts which are part of the "TEST PROTOCOL - [redacted] P/N [redacted], document number [redacted], Revision [redacted] dated [redacted]. I stated that there is no clear delineation between the [redacted] molded parts which are contained within this study and these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L60 is the [redacted]

[redacted] Page [redacted] indicates that this laboratory number [redacted]) identifies the sample taken from process number [redacted] This documents the sterility of this batch of parts.

Exhibit L61 is a TRAINING DOCUMENT procedure entitled "ENVIRONMENTAL AND ACCELERATED AGING TEST"; procedure number [redacted], Revision [redacted] dated [redacted]. Page [redacted], Section [redacted] states that [redacted]

[redacted] Mr. Shirley stated that this procedure was followed for this experiment and is what is referenced within the test report.

The test report stated that ".. [redacted] day environmental cycle was completed..." (Exhibit L52, Section [redacted]. However, it was noted that in the protocol (Exhibit L51, Section [redacted] that the

environmental cycle was specified to be carried out under the conditions as follows: place the parts and assemblies in the environmental chamber and cycle the temperature between ——— for — days. There is no documentation to support the temperature cycling.

Mr. Shirley provided Exhibit L62 when he was asked to provide documentation that the environmental cycle was conducted in accordance with the test protocol. This exhibit is a page from the "Environmental Cycle Log" and the entry that Mr. Shirley identified as the one associated with this experimental test is dated ———. The product is identified as ——— and the estimated date out is documented as ——— I stated that ———is a total of — day exposure to the environmental chamber and the protocol (Exhibit L51, Page , Section—) indicates that the cycle is approved for ' ——— Therefore, this environmental cycle was not conducted in accordance with the established protocol.

There is no documentation or data to support that accelerated aging took place on the parts during this study. The test report states that ——— The test protocol (Exhibit L51, Section —— states to conduct accelerated aging as ———

———"

It was noted that the parts were released from molding on —— per Exhibit L54, Page which is the Bill of Operations – BOO (Procedure: ' ———dated —— for part number ——— The environmental cycle took place between ——— , according to Exhibit L62 provided by Mr. Shirley. The parts were subjected to — sterilization between——— According to the above mentioned test protocol, the parts were to be — sterilized and then subjected to environmental cycling. According to the documents provided by Mr. Shirley and discussed above, the parts were subjected to the environmental cycle prior to being subjected to——sterilization.

In summation, the current Bill of Operations (Process No. ——— , Operation —states to anneal parts ———, to procedure ——— . Manufacturing procedure ——— , entitled "HEAT ANNEALING PROCEDURE", Rev. , dated ——is found as Exhibit L63. Section , Page states to preheat oven to ——— degrees Fahrenheit (section —, and place trays in preheated oven for ——— (section —. The annealing process qualification associated with molded part (P/N ———r) is not complete in that data/documentation does not exist associated with the qualification/validation study associated with the annealing oven.

Exhibit L64 is the current annealing procedure which is currently being utilized during injection molded parts manufacturing ——— Manufacturing procedure ———entitled "HEAT ANNEALING PROCEDURE", Rev. —dated ——— The annealing oven operational parameters are the same as mentioned above and found within the procedure within section ——Page ———

Exhibit L65 is a promotional material page from an industrial bench oven catalog entitled [redacted] which provides a description for the model [redacted] oven which is currently being utilized by the firm to [redacted] rts. Mr. Shirley provided this information and indicated that it is associated with the annealing oven which is currently being utilized by the firm.

The management of the firm was informed on 3/1/04, at which time my review of the injection molding operations and associated procedures/documents had been concluded, that injection molding validation (processing tolerance limits, sampling plan, installation of processing equipment, material drying process, annealing process, etc.) would be cited as an observation on the FDA-483, Inspectional Observations.

A second item found within this observation is stated on the FDA-483 as "Additionally, this same test report documents qualification for the [redacted] bonding process used to assemble [redacted] tubing to [redacted] connectors in the Deltran assembly. The raw data supporting this summary report was not retained." See the section of this report entitled "BONDING PROCESSES" for additional information associated with the firm's bonding operations.

This point was addressed and this section of the EIR was written by Investigator Jerndal.

I requested validation documentation for this bonding process. Mr. Shirley supplied Test Report [redacted] Revision [redacted], dated [redacted] attached as Exhibit R57, and Test Protocol [redacted], Revision [redacted], dated [redacted]; [redacted] P/N [redacted], attached as Exhibit R58. This Test Protocol states, [redacted] Mr. Shirley stated that the testing also supports the bonding operation in question. Exhibit R58 protocol states on page [redacted] Acceptance Criteria Section [redacted]

The Exhibit R57 Test Report summarizes the result of [redacted] analysis done on [redacted] samples. We requested the raw data to review, in part to answer this question. Mr. Shirley stated that the raw data was not maintained and is not available for review. Additionally, the engineer performing this work is no longer in the employ of the company. This test report notes on page [redacted] Section [redacted], that [redacted] year accelerated aging, completed [redacted], was performed and found acceptable; again, the raw data has not been kept and is not available for review. According to Mr. Shirley, the [redacted] Corrective Action affects all of the DELTRAN products manufactured and all of the [redacted] bonded connector joints. The various versions of DELTRAN are illustrated with the engineering drawings on pages [redacted] of Exhibit R84.

FDA-483 ITEM NUMBER 1e: Written by Investigator Jerndal.

INTRAN PLUS — Adhesive Bonding

I asked to review the validation supporting the — adhesive bonding of the — in the INTRAN Plus IUP fetal monitoring product family assembly, illustrated in Exhibit L11. Exhibit R59 is the Engineering Drawing for this assembly, "INTRAN Plus IUP-X00 Assembly", Revision —, Exhibit R60 is the Manufacturing Procedure — Revision —, dated — "INTRAN Catheter — & Install Introducer." This procedure directs this bonding operation. The tubing in question is the Part — tubing extruded In-house. This — Mr. Shirley stated that this bonding operation was qualified as part of the — Material Qualification performed for the extrusion molding process. Those documents describing this include the Exhibit R45 Test Protocol, — dated —, and Exhibit R46 Test Report, — 11/09/95.

Exhibit R46, Pages — is the — Item #10 references, — on pages — This summarizes pull strength test result data for various groupings of — samples. Mr. Shirley presented these test reports as supporting this specific bonding operation. No specific discussion or description of the relevancy was offered. I requested documentation supporting continuity with the currently performed bonding process. Mr. Shirley supplied me with Engineering Change Request — dated — attached here as Exhibit R61. It involves the change from — for the — dispenser used in this bonding operation with a reason given as, "To keep the syringe and adaptor from getting clogged." Attached to this Exhibit R61 is the — procedure Revision Change from — of that time period in 1995. Mr. Shirley also supplied a copy of a Bill of Materials for the IUP-400 INTRAN Plus Catheter dated —, attached as Exhibit R62. Mr. Shirley offered no specific explanation as to how these early documents assert continuity with currently applied process other than to presume the process remains similar.

This bonding operation is called out as Line #11 illustrated on Bill of Operations Revision — Work Order — Exhibit R44. Subsequent testing during this — assembly is called out on line — the final test done per —. A copy of this procedure, Revision — dated — — Final Test", is submitted here as Exhibit R63. This is the final electrical testing and — functional test for the — catheters. According to Mr. Shirley, Utah Medical has done no additional qualification assessment or testing of this bond since that reference in the above — Materials Qualification.

INTRAN PLUS — Bond

I selected an — bond also from the — Assembly process for review. This bonding operation is directed by the Manufacturing Procedure — Revision — dated — — - Insert & —, attached here as Exhibit R64. This

operation is performed, as called out on line of Exhibit R44 Bill of Operations. Testing performed following this operation include the final testing per discussed above, and the testing done per Exhibit R41. This latter test assesses the catheter body independent of the parts associated with this

I requested documentation supporting validation of this bonding process. Mr. Shirley supplied me with the following documents:

- Exhibit R65, memo from Dated subject: Project Update.
- Exhibit R66 Test Protocol Revision , dated (This protocol's reported purpose on page states, "Performance tests the product structurally and functionally after sterilization and aging").
- Exhibit R67 "Master Test Plan for , dated
- Exhibit R68 lab book test data, dated (pull test data on page
- Exhibit R69, Test Protocol revision dated Master Test Plan (page , section .

Mr. Shirley confirmed that there has been no additional testing done since that performed in the late 1980s as described above.

I observed this bonding operation and verified their current use of what appears to be the original A single operator, who mounts each into which the component is then placed, performs this operation. The operator then presses the two actuating switches and the and over the component. The welding energy, duration, and alignment are pre-determined, automated and independent of the operator. Each part is then examined by the operator visually. Mr. Shirley commented that this bonding operation is a very stable process and that the connection between these two parts would meet their test requirements without

FDA-483 ITEM NUMBER 1f: Written by Investigator Jerndal.

Exhibit R12, Revision , dated "Material Dryer Cleaning & Startup" defines the material dryer startup requirements on page , Section . Section identifies the BOO (Bill of Operations) as the document specifying the requirement for material drying. Exhibit R27, Revision 3OO, line states, There is no maximum dry time established. Exhibit R4, Work Order ; start date Assembly ncludes the BOO Revision that notes on line There is no established maximum dry time for this extruded part. In this case, the BOO indicates the material was put into the dryer hopper on The first "QUALITY ASSURANCE INSPECTION REPORT" Sheet (Exhibit R4, Page 10) shows the process extrusion startup at It appears that in this case, the material remained in the dryer for hours prior to

startup. I asked Mr. Shirley if there were a maximum limit on the time material could be kept in the dry prior to use. Mr. Shirley stated that there was no maximum specification established. I asked Mr. Shirley what the affect of this long dry time was on this material. Mr. Shirley speculated that over drying could result in the resin becoming sticky and that this might inhibit the flow of material into the extruder hopper. Mr. Shirley stated that this would not be a problem as the extrusion process could not go forward if the material were not moving into the extruder hopper.

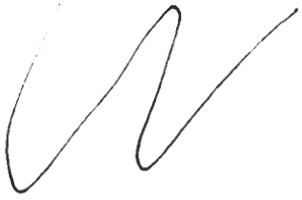
Discussion with management FDA-483 item number 1:

a) Written by Investigator Jerndal. During the exit interview and presentation of the FD-483, none of the parties present or on phone linkup had any questions or responses concerning the 483 citation #1A, other to indicate they understood the issue.

b) Written by Investigator Medina. Ben Shirley, Quality Manager, stated that the injection molding processing tolerance limits (temperatures, pressure, speed, injection time) have not been challenged since the installation of the equipment in) — He stated that the firm has (in their opinion) documentation to support that the process in operating within a state of control. The documentation to support the firm's position is found as follows:

EXHIBIT	DOCUMENT	DESCRIPTION
L66	Drawing Number — Rev. —, dated — entitled	P/N — drawing and part specifications (dimensions)
L67	Bill of Materials; Procedure number —, dated — for	Part number; revision, quantity, references, ECO No. which specifies the material needed to manufacture this part
L45	"BOO" (Bill of Operation) for ' dated — (Process)	Operation number; work center; operation description which describes the manufacturing steps for the injection molded parts.
L17	"MOLDING SET-UP SHEET" for machine number ; Part Number Connector, Female, , SETUP SHEET ; Rev. (undated)	This is a representative example of an injection molding operational set-up sheet which includes processing equipment parameters.

L20	"Control Chart for Variables" for Part number — entitled [redacted] ; SPC —, Revision, —	Contains control limits for Mean and Range (LCL and UCL). Additionally, a sampling plan is specified for a sampling interval of — hours and a sample size of [redacted]
L21	"Attribute Inspection Form" for Part number — entitled [redacted] "; SPC — Revision —	Contains visual inspection defect descriptions for flash, incorrect luer taper, short shot, and others. Additionally, a sampling plan is specified for a sampling interval of — hours and a sample size of [redacted]
L18	FORM SPECIFICATION number — RUN SHEET-MOLDING; Revision — dated [redacted]	The "RUN SHEET" (Page —) documents the processing information (but not limited to) as follows: [redacted]
L19	TRAINING DOCUMENT number — entitled "INJECTION MOLDING PROCESS SET-UP AND PRODUCING PART", Revision — dated —	Contains injection molding process set-up instructions (Page —, producing parts (Page —); and completing injection molding work orders (Page —). Section — states to " [redacted] Section — states ' [redacted]

		
L68-L79	"Certificate of Calibration" from [redacted]; Instrument Data Report; and Preventive Maintenance documents	A representative example of injection molding equipment "Certificates of Calibration" and Preventive Maintenance on machine numbers as follows: [redacted]

(*) Representative Injection Molding Equipment Calibration and Preventive Maintenance documentation summary:

EXHIBIT	MACHINE	DOCUMENT	DATE
L68	[redacted]	"Certificate of Calibration" from [redacted] and Instrument Data Report (Code [redacted]	[redacted]
L69	[redacted]	Preventive Maintenance documents	[redacted]
L70	[redacted]	"Certificate of Calibration" from [redacted] and Instrument Data Report (Code [redacted]	[redacted]
L71	[redacted]	Preventive Maintenance documents	[redacted]
L72	[redacted]	"Certificate of Calibration" from	[redacted]

		and Instrument Data Report (Code	
L73		Preventive Maintenance documents	
L74		"Certificate of Calibration" from and Instrument Data Report (Code	
L75		Preventive Maintenance documents	
L76		"Certificate of Calibration" from and Instrument Data Report (Code	
L77		Preventive Maintenance documents	
L78		"Certificate of Calibration" from and Instrument Data Report (Code	
L79		Preventive Maintenance documents	

Mr. Shirley also stated that there is no documentation to support that process equipment [redacted] was properly installed in [redacted] Validation activities have not been conducted on the [redacted] programmable logic control system utilized to establish actual operating parameters of the injection molding equipment. Additionally, he stated that the firm has (in their opinion) documentation to support that test sampling plan was based upon a statistically valid rationale ([redacted] This documentation exists in the SPC sampling scheme (see FDA-483 item numbers 2a and 2b and the Objectionable Conditions section of this report) associated with injection molded parts. The firm's response to this observation (from the 2003 inspection) is found as Exhibit L10 (section 1D). Exhibit L10, Page 20 (memo associated with this corrective action) states that the firm "...has contacted outside 'experts' in the field of plastic forming for medical devices to seek additional input regarding what additional activities the company should undertake to 'validate' its (molding) process. [redacted]

Mr. Shirley stated that his firm is "confident" that the experts will find that the firm's injection molding operations are in control. During this inspection (on 2/24/04), Investigator Medina asked Mr. Shirley to provide information associated with the "experts" as follows: name; the date(s) information was provided to them; what services they were contracted to provided; and the information/data that was provided to them for review. Mr. Shirley stated that he could not provide this information to me during this inspection. On 3/1/04, Mr. Cornwell stated that some information, since the previous inspection, was provided to the experts for review.

c) Written by Investigator Medina. Ben Shirley, Quality Manager, stated that the [redacted] material drying process (utilized during injection molding) has not been qualified or validated. Mr. Shirley provided the material specification sheet and stated that the processing of material above the established limits was an oversight. A Non-Conforming Material Report (NCMR) was established during this inspection to address this processing deviation.

Exhibit L80 is NCMR number [redacted] dated [redacted] (referencing [redacted]; Lot number [redacted]) which states that the description is "...OUT OF SPECIFICATION. [redacted] A hand written statement (dated [redacted] indicates that [redacted] There is no scientific documentation or data to support this decision to use as is.

On the bottom of the above mentioned NCMR is a handwritten note dated [redacted] which states to '[redacted], document number [redacted] dated [redacted]

The lot numbers associated with this document are [redacted] The description of the deviation/waiver ([redacted] is stated as ' [redacted] There is no scientific documentation or data to support this decision to use as is.

d) Written by Investigator Medina. Ben Shirley, Quality Manager, stated that data/documentation does not exist associated with ' [redacted] , Rev. [redacted] dated [redacted] and [redacted] Rev. [redacted] dated [redacted] However, he stated that the firm has improved upon the manner in which they maintain data and documentation associated with validation/qualification studies which have been conducted since that time.

e) See the above discussion found within the "Relevance/Additional details of the observation" section associated with FDA-483 item number 1e.

f) See the above discussion found within the "Relevance/Additional details of the observation" section associated with FDA-483 item number 1f.

Related samples and exhibits:

A documentary sample (number 68796) was collected to document the manufacturing, sterilization, and interstate shipment of a finished IUP medical device and associated deviations from the Quality System Regulation. The IUP device contains injection and extrusion molded components.

The exhibits relevant and related to this observation include the Exhibits as follows: L10; L11; L13; L17-L25; L27-L81; R4; R12; R24; R27-R30; R41; and R44-R88.

OBSERVATION 2

Acceptance procedures to ensure that specified requirements for in-process product are met were not documented.

a) **Injection molded parts (P/N [redacted]) were not processed in accordance with procedure number [redacted] Revision [redacted] entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated [redacted]. Section [redacted] states to [redacted] above UCL or below LCL). Processing above the UCL was observed in [redacted] work orders for injection molded parts (P/N [redacted] manufactured between [redacted] The established product characteristic specification parameters for P/N [redacted] are [redacted] inches.**

1) **Work order number — On — and — , injection mold manufacturing (P/N —) was documented as having — and — — , points above the established UCL — respectively.**
2) **Work order number — On — and — injection mold manufacturing (P/N — was documented as having — and — — points above the established UCL — respectively. NCMR — dated — documents that —**

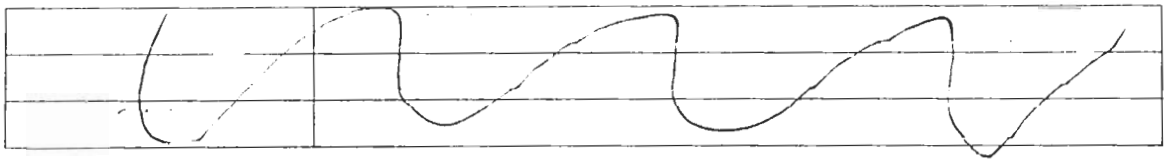
b) **Work order number — (P/N — (documenting the actual injection molding equipment set up parameters) dated — documented that the — differed from the — (established parameters). The — established parameter is — in and the actual set-up was — in. The — established parameter is — and the actual set-up was — This was observed in — work orders for injection molded parts (P/N — manufactured between —**

Reference: 21 CFR 820.80(c)
Relevance/Additional details of the observation:

FDA-483 ITEM NUMBER 2a: Written by Investigator Medina.
Exhibit L82 is — — , Revision — entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated — which describes a procedure to measure physical and cosmetic characteristics of the injection molded parts. Section — states to — (above UCL or below LCL). Page Section — states that a process shift is indicated as — Exhibit L83 is Revision — (the previous version) of the above mentioned procedure dated — and is included within this report as reference. Mr. Shirley stated that the above mentioned procedure is utilized for the production of all injection molded parts that are manufactured by the firm.

Exhibit L82, Page — Section — is entitled "VARIABLE INSPECTION PROCEDURE" and section — instructs the inspector to — A summary of the process shift criterion is as follows:

SECTION/Page —	PROCESS SHIFT
—	—



Section — Page —tates ' — Additionally, section — states that the —

During a review of work orders associated with the manufacturing of injection molded parts, processing above the UCL was observed in ' — work orders for injection molded parts (P/N —) manufactured between · —. The established product characteristic specification parameters (specification limits) for P/N — are — to — nches per Exhibit L20 entitled "Control Chart for Variables". Exhibit L66 contains the specification for the inner diameter of the tubing pocket which is — per the applicable drawing for P/N

FDA-483 ITEM NUMBER 2.a.1: Written by Investigator Medina.

Work order number — On — and —, injection mold manufacturing (P/N —) was documented as having (—) and —) points above the established UCL — inches) respectively.

Exhibit L24 contains documentation associated with the manufacturing of work order number — of injection molded parts (P/N — Documentation is as follows:

EXHIBIT/PAGE(S)	DOCUMENT DESCRIPTION
L24/1-3	WORK ORDER TRAVELER
L24/4	RUN SHEET
L24/5-6	MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page— MOLDING SET-UP SHEET (established set-up specifications)
L24/7-38	Control Chart for Variables and Attribute Inspection Forms for processing which occurred between —

The "Control Chart for Variables" (SPC — and "Attribute Inspection Forms" (SPC —) document actual injection molding processing testing for P/N— According to the — Revision —entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated — (Exhibit L82), the operation identified in section —for ' — which

indicates a process shift was not noted and there is no documentation to support that (according to Section — of the procedure) that [redacted]

[redacted] There is no documentation to support that a room supervisor or engineer was notified and that the parts were quarantined. Additionally, section — states that the [redacted] " (Page — There is no documentation that this occurred. A summary of part testing documentation is as follows:

EXHIBIT/PAGE(S)	DATE	ISSUE
L24/7	—	— samples documented as being above the established (Mean) UCL of — as follows: [redacted]
L24/11	—	— samples documented as being above the established (Mean) UCL of —, as follows: — [redacted]
L24/17	—	—, samples documented as being above the established (Mean) UCL of — as follows: [redacted]
L24/21	—	—, samples documented as being above the established (Mean) UCL of — as follows: [redacted]
L24/27	—	— samples documented as being above the established (Mean) UCL of — as follows: [redacted]
L24/33	—	— samples documented as being above the established (Mean) UCL of — as follows: — [redacted]

Exhibit L24, Page Operation documents that these materials were processed under

(change proposal). (dated) is found as Exhibit L24a which addresses the description of change as There is no reference to the UCL SPC limit being exceeded and there is no documented approval of these parts of being acceptable to have been processed above the established UCL.

FDA-483 ITEM NUMBER 2.a.2: Written by Investigator Medina.

Work order number On and injection mold manufacturing (P/N was documented as having r and points above the established UCL respectively. Exhibit L44 contains NCMR dated documents that

Exhibit L25 contains documentation associated with the manufacturing of work order number of injection molded parts (P/N . Documentation is as follows:

EXHIBIT/PAGE(S)	DOCUMENT DESCRIPTION
L25/1-3	WORK ORDER TRAVELER (copy unreadable except for part label and total quantity; best possible copy obtained)
L25/4	RUN SHEET
L25/5-6	MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page MOLDING SET-UP SHEET (established set-up specifications)
L25/7-28	Control Chart for Variables and Attribute Inspection Forms for processing which occurred between , IN-PROCESS MOLD MAINTENANCE

The "Control Chart for Variables" (SPC and "Attribute Inspection Forms" (SPC 8 document actual injection molding processing testing for P/N 1 According to the , Revisior entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated (Exhibit 82), the operation identified in section for which indicates a process shift.

Exhibit L44 is Non-Conforming Material report (NCMR) number (P/N , lot number dated documents that A handwritten note on the

NCMR states [redacted] dated [redacted] Additionally, on [redacted] the NCMR had a handwritten noted added which read [redacted] The drawing specification is found as Exhibit 66. The established product characteristic specification parameters (specification limits) for P/N [redacted] are [redacted] to [redacted] inches per Exhibit L20 entitled "Control Chart for Variables". Exhibit L66 contains the specification for the [redacted] which is [redacted] per the applicable drawing for P/N [redacted] This NCMR was "closed & filed" on [redacted]

Exhibit L84 is a "CHANGE PROPOSAL" number [redacted] dated [redacted] in which the description of change is to [redacted] in molding (referencing SPC [redacted]) and [redacted] The reason for the change states [redacted] At the beginning of this inspection, the SPC chart had not been recalculated per this Change Proposal.

During this inspection, the SPC chart for injection molded part number [redacted] was changed. Documentation to support this SPC product sampling specification change is as follows:

EXHIBIT	DATE	SPC SPECIFCIATION CHANGE DOCUMENT AND ISSUE
L84 (Page 3)	Release dated [redacted]	CHANGE PROPOSAL number [redacted] ([redacted] Supporting documentation included in Pages [redacted] reason for change documented as [redacted] .." (as found as originally calculated in Exhibit L88).
L85	Release dated [redacted]	CHANGE PROPOSAL number [redacted] corrected version on document; revision was not changed when the document was.
L86	Undated	Data utilized by the firm to recalculate the SPC chart; calculated using data from work orders as follows: [redacted] Work order numbers found on top of sheet.
L87	Undated	"Steps for Constructing [redacted] which contains the formula for calculate SPC (according to Ben Shirley).
L88	[redacted]	CHANGE PROPOSAL number [redacted] nitial release of attribute and variable charts for P/N [redacted] SPC

		Release date

As was noted in item a), there is no documentation to support that (according to Section of the procedure) that ' ' There is no documentation to support that a room supervisor or engineer was notified and that the parts were quarantined. Additionally, section states that the ' ' There is no documentation that this occurred. A summary of part testing documentation is as follows:

EXHIBIT/PAGE(S)	DATE	ISSUE
L25/7		samples documented as being above the established (Mean) UCL of as follows:
L25/13		samples documented as being above the established (Mean) UCL of as follows:
L25/17		samples documented as being above the established (Mean) UCL of as follows:
L25/23		samples documented as being above the established (Mean) UCL of as follows:

There is no reference that the room supervisor or the engineer was notified in either of the above mentioned cases. Additionally, there is no documentation that the room supervisor adjusted the control parameters of the equipment to ' ' (Exhibit L82, Page Section

In summation, injection molded parts (P/N were not processed in accordance with procedure number Revision entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated .

The SPC charts (in-process testing) currently being utilized by the firm include the physical testing of injection molded parts for dimensional attributes and are not an indicator of monitoring injection molding processing parameters for process shifts. The firm refers to this "physical testing" for attributes operation as "SPC" which is an in process dimensional check of injection molded parts.

FDA-483 ITEM NUMBER 2.b: Written by Investigator Medina.

Work order number [redacted] (P/N [redacted] (documenting the actual injection molding equipment set up parameters) dated [redacted] is found as Exhibit L24, Page [redacted] The documented [redacted] s found on the [redacted] differed from the [redacted] found as Exhibit L24, Page [redacted]

The [redacted] established parameter is [redacted] in (Exhibit L24, Page [redacted] and the actual set-up was [redacted] in. (Exhibit L24, Page 5). The [redacted] established parameter is [redacted] sec (Exhibit L24, Page [redacted] and the actual set-up was [redacted] sec. (Exhibit L24, Page [redacted] This was observed in [redacted] work orders for injection molded parts (P/N [redacted] manufactured between [redacted]

During the inspection, it was also noted that several other actual operational parameters differed from the established set-up for injection molding P/N [redacted] A summary of these differences is as follows:

- DOSQ (Reference) HP
- Option Mold Opening (Reference)
- Timer, Counter (Reference)

Mr. Shirley stated that these are "reference" settings only.

Discussion with management FDA-483 item number 2:

Written by Investigator Medina.

a) Mr. Shirley stated that the firm has recalculated the SPC sampling associated with P/N [redacted] He agreed that work order number [redacted] 2 was processed above the UCL and was not noted by the firm as being processed under this condition. However, work order [redacted] had an NCMR and Change Proposal associated with it which identified that the SPC was out of control. I indicated that there is no reference that the room supervisor or the engineer was

notified and there is no documentation that the room supervisor adjusted the control parameters of the equipment to "eliminate the cause of the shift..."

b) Mr. Shirley stated that this was an oversight and that the injection molding processing parameters were not observed by the Quality Assurance reviewer to be documented outside of the established limits.

Related exhibits:

A documentary sample (number 68796) was collected to document the manufacturing, sterilization, and interstate shipment of a finished IUP medical device and associated deviations from the Quality System Regulation. The IUP device contains injection molded components.

The exhibits relevant and related to this observation include the Exhibits as follows: L20; L24; L24a; L25; L44; and L82-L88.

OBSERVATION 3

Software validation activities for computers or automated data processing systems used as part of production and the quality system have not been documented.

The following computer software has not been validated for its intended use

For example,

a) **The complaint handling system including the Software program, Version has not been validated for its intended use. The firm uses the complaint handling system to enter complaint records by capturing the complaint details and investigation information in the software program. In addition to the data entry functions, the firm uses the Summary Reports functions. The data from the reporting function is exported to spreadsheets from the . Complaint Handling System to generate reports for the Material Review Board (MRB - CAPA Committee) Reviews including the reports such as The firm's Software Validation Master Plan schedule, updated on , indicates the Test Protocol is in the drafting phase and designates the criticality as high for planning priority.**

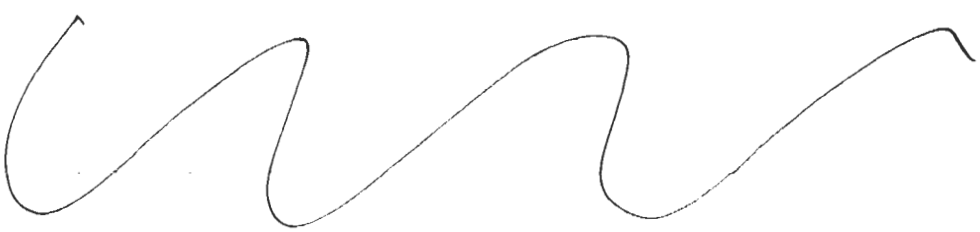
b) **The spreadsheets used to record logs of Corrective and Preventive Action Reports, Deviation Waivers, and Nonconforming Material Reports have not been validated for the intended use. The spreadsheets are used to present data for the Material Review Board Reviews (CAPA Committee)**

. In addition, the data is imported into ——— Spreadsheets from the ——— Complaint Handling System to generate reports for the MRB Reviews including the reports such as ———

———The firm's Software Validation Master Plan schedule, updated on ——— indicates the Test Protocol is in the ——— phase and designates the criticality as high for ———

c) **The ——— system, Version —— has not been validated for its intended use as follows:**

The firm's Software Validation Master Plan schedule, updated on ——— does not indicate the current status of the Test Protocol and designates the criticality for planning priority and planned completion date as follows:



Reference: 21 CFR 820.70(i)

Relevance (Observations 3a and 3b):

FDA-483 ITEM NUMBER 3a and 3b: Written by Investigator Wilkins.

The information provided below outlines the review process for the computer systems used for quality data.

On 02/10/04 at approximately 8:40 a.m., I, Investigator Wilkins, request to observe and verify the databases used for quality data including databases used to for the Corrective and Preventive Action

system. Mr. Ben Shirley states he does not think he can show me the systems. The firm's consultant, [redacted] states that it is not usual for FDA to look at the databases and computer systems. In response, I explain that it is a routine inspection practice and a part of the FDA inspection process to verify the databases, computer systems, and other software tools used to store and capture quality data. Later that day Mr. Shirley and [redacted] state they will check for the data sources and then show me the information. I again state that I need to view the actual systems used.

Later that day, approximately 1:40 pm, [redacted] states he compiled the information on how the data sources are used, but that it is company policy not to run reports that are requested by the FDA. [redacted] states he will review the information he collected with me in the conference room. I explain that I will listen to his presentation of information, but that I will still need to verify the information myself by observing the actual systems used. [redacted] then states that if a request is made to run a report from those systems, FDA would have to put the request in writing and come from our supervisors and then go through the company's general counsel. I state that if we are to make a request it will be a verbal request from the investigators as we are the individuals conducting the inspection and it is the company's choice to discuss the issue with their counsel. At this time, [redacted] provides the requested [redacted] Users Manual and states he will gather the necessary individuals and left the conference room.

Towards the end of the work day, Mr. Shirley and [redacted] state they will take me to a computer terminal to allow me to observe the systems used. We begin with the [redacted] system and I ask to observe the screens, menus, and functions used. When asked to view a specific complaint on the system, Mr. Shirley states he will not do it because I am verifying the data and I stated I would not do a verification. I explain that it is part of the process to look at the data fields and by not providing the information it was considered a refusal. Mr. Shirley then states that they do not have to show us any of the files as their attorney has stated as such. I state that if he continues to place obstacles in our review, I will ask for the electronic databases to be downloaded on disk for us to view the information. Mr. Shirley then states that he knows companies do not have to provide the information. I ask if he is refusing to provide the requested information. [redacted] interjects that FDA can get an inspection warrant and that the company will provide the information, but that they need time to discuss the issue.

We continue viewing some of the screens, but Mr. Shirley is unable to provide the information I request to observe or provide the functional information of the system. [redacted] requests we end for the day and resume the review the next day because they would have to speak to some of the individuals that use the system and they are gone for the day.

On the morning of 02/11/04, [redacted] states he has some of the information pertaining to the [redacted] and some of the spreadsheets used by the company. He verbally provides some of the information, but I again state that I need to verify the information myself by observing the systems. As Mr. Shirley is our only point of contact and the only individual allowed to answer

questions, the other investigators need time to request information from Mr. Shirley, I return to the review of sterilization records.

At approximately 2:40 p.m. on 02/11/04, I request the software and computer systems validations for the following:

- Document Distribution System
- [redacted]
- [redacted]
- [redacted]
- [redacted] Hole Drilling
- Finesse [redacted] Revision
- Software [redacted] Final Tester

A while after my request, I am provided with a memorandum, dated [redacted], concerning the Software Validation Plan, refer to Exhibit #M1 Page [redacted] The memorandum includes an attached procedure titled, Software Development, Validation, and Documentation, Document No. [redacted] Revision [redacted] Revision Date [redacted] refer to Exhibit #M1 Pages [redacted] The memorandum also includes a Software Validation Plan schedule with updated versions dated [redacted] refer to Exhibit M1 Pages [redacted] and respectively. The most current Software Validation Plan schedule, revision date [redacted] indicates the [redacted] and [redacted] systems are assigned a criticality priority of "high" and that the testing protocols are in the [redacted], refer to Exhibit #M1 Page [redacted]

After reviewing the Software Validation Plan, Revision Date [redacted] I requested the Test Protocols for the [redacted] and [redacted] software programs. Mr. Shirley stated the [redacted] Test Protocol is still in the [redacted] Mr. Shirley provided a [redacted] copy of the [redacted] Validation Test Protocol, Document No. [redacted] Revision [redacted] refer to Exhibit #M2. I reviewed the [redacted] Test Protocol, but did not comment on any issues as the protocol is a draft version.

Towards the end of the day on 02/11/04, Mr. Shirley and [redacted] I state they are ready to take me to a computer terminal to review the computer systems used for quality data. I am able to verify the rest of the information on the use of the [redacted] system, but I am unable verify and view other data sources such as the [redacted] Spreadsheets or the Document Distribution System. We have another discussion on allowing the verification of the data sources. Once again, I ask if they are refusing to allow the verification of the systems used. [redacted] and Mr. Shirley state that it is a misunderstanding and that they will show me the data sources tomorrow as it is late and the individuals are gone for the day.

PURGED

On 02/17/04, I resume my review of the computer systems used for quality data as I was unable to continue the review earlier as the other investigators needed time with Mr. Shirley and in the meantime I continued the review of the sterilization process. On this day, Mr. Cornwell states he docs not have individuals available to pull documents for us as he had requested an inspection break from 02/17/04 through 02/23/04. I explain that we will continue with the inspection process and request the Document Distribution System Protocol, Summary of Validation, and the data associated with the validation of the system. Later that morning, Mr. Cornwell provides the Document Distribution validation data.

On the afternoon of 02/17/04, at approximately 2:45 p.m., Mr. Cornwell states he cannot accommodate any additional document requests as he spent half the day chasing down the information we requested earlier. At this time Investigator Medina states FDA management has agreed to grant his request to resume the inspection on 02/23/04. I state that before we agree to such a break, we need assurances that he will provide personnel to answer questions, review documents with each investigator, and pull the requested records to expedite the inspection. Mr. Cornwell states he will have the necessary individuals available. We agree to resume the inspection on 02/23/04 and leave for the day.

On 02/23/04, we resume the inspection and Mr. Cornwell provides a blue binder that contains responses to the observations cited during the 2003 inspection. The blue binder contains information similar to that provided during the previous days for the software validation activities. I continue the review of the computer systems used to document quality data. The information includes a memorandum (Exhibit #M3 Pages —, dated —, concerning software validation activities and an updated Software Validation Plan (Exhibit #M3 Page—, Revision Date — The updated Software Validation Plan, Revision Date — contains the same information concerning the —and — programs as the Software Validation Plan, dated — During our discussions throughout the day, I informed Ben Shirley that the— —and —functionality used for quality data would be recited on the FDA-483 as observations because the validations have not been executed or completed.

As described above, during the period between 02/10/04 through 02/23/04, I reviewed the records and related computer systems used for quality data. A verification of the software program currently used by the company for the complaint handling system revealed they are using the — Software Program, Version , to enter, store, and retrieve data on complaint records. In discussions held with Mr. Shirley, —and later with Mr. Cornwell, it was established that the firm's official record is the paper (hard) copy of the complaint file, but the information from the complainant is entered directly into the system.

As an example of the type of data entered into the —, Complaint File Number — is attached to this report, refer to Exhibit #M4. The categories of information entered into a complaint file in the — system include the —

Also, a template for the MedWatch form is available in the [redacted] system and the company uses the template form to enter and complete the medical device report information, refer to Exhibit #M4 Pages [redacted]. Once the form is completed, it is printed and the paper copy becomes the official record.

One person, [redacted] Complaint Coordinator, enters all complaints received by the company and provides the information for the Material Review Board Quarterly Reports for CAPA data. [redacted] has system access rights as the Complaint Coordinator so that he can perform data entry, query reports, and review the information. The Quality Assurance Manager has access rights to include the closure of complaints.

The [redacted] : User Manual, Version [redacted] provided by [redacted] on 02/10/04, indicates there are [redacted] levels for user security. The user security levels are as follows:

The Data Entry access level only permits the entry of basic complaint information, but does not allow the entry of information related to the investigation of complaints or to modify complaints.

The Analyst access level permits the entry of basic complaint information, investigation of a complaint, entry of MedWatch reports, generate all reports, and re-open complaints that have been closed.

The Read Only access level permits view only access to the complaint and investigation information, but allows the generation of all reports.

The Administrator access level permits the entry of basic complaint information, investigation of a complaint, entry of MedWatch reports, generate all reports, and re-open complaints that have been closed. In addition, the users with the Administrator access level have the ability to maintain lists of products, manufacturing sites, perform database maintenance, and control user accounts and security level. These users have the ability to delete and re-open complaints from the database.

The firm controls the user accounts and security level by passwords. A review of the system with Mr. Shirley and [redacted] confirmed that [redacted] levels of passwords are needed to gain the security level of access designated for the individual. The review of the system also confirmed the firm is using the system to enter complaint information, investigation information, generate the MedWatch hard copy completed form, and generate administrative reports through the use of the summary reports function.

In addition, [redacted] and Mr. Shirley provided information to confirm that data from the [redacted] summary reporting function is exported to [redacted] spreadsheets from the [redacted] Complaint Handling System to generate reports for the Material Review Board (MRB - CAPA Committee) [redacted] Reviews. The reports generated in this manner include the following:

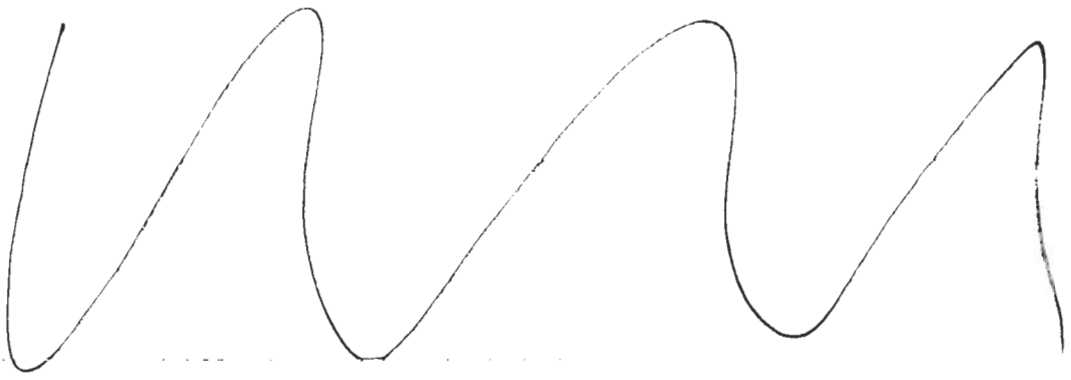
[redacted]

As mentioned previously, the initial document provided for the Software Validation Plan schedule, updated on [redacted], indicates the [redacted] Test Protocol is in the [redacted] designates the criticality as "high" for planning priority, and provides an estimated planned completion date of [redacted] Mr. Shirley stated they were behind schedule and due to the FDA inspection have not had time to continue their work on the software validations.

The company's management was informed on several occasions, including [redacted] that the lack of completing the validation of the [redacted] System would be cited as an observation on the FDA-483 form. A similar observation was cited during the [redacted] inspection, but the company has not completed the validation of the [redacted] System. The firm does have a software validation plan in place, a [redacted] Test Protocol, and is in the process of performing a validation.

The company also uses the [redacted] software program to create spreadsheets, which are used as record logs of [redacted], refer to Exhibit #M6, Exhibit #M7, and Exhibit #M8, respectively. The [redacted] spreadsheets are also used to present data for the Material Review Board (MRB) Reviews (CAPA Committee). Examples of the spreadsheets used for the MRB [redacted] Reports are as follows:

[redacted]



In addition, data exported from the [redacted] System is imported into [redacted] Spreadsheets to generate reports for the MRB [redacted] Reviews including the reports such as [redacted]

The initial document provided for the Software Validation Plan schedule, updated on [redacted] indicates the [redacted] Test Protocol is in the [redacted] designates the criticality as "high" for planning priority, and provides an estimated planned [redacted] Mr. Shirley stated they were [redacted] due to the FDA inspection and have not had time to continue their work on the software validations.

The company's management was informed on several occasions, including 02/23/04, 02/27/04, 03/01/04 and 03/02/04, that the lack of completing the validation for the intended use of the [redacted] program would be cited as an observation on the FDA-483 form. A similar observation was cited during the 2003 inspection, but the company has not completed the validation for its intended use of the [redacted] program. The firm does have a software validation plan in place and is in the [redacted], a testing protocol for the validation.

Discussion with Management (Observations 3a and 3b):

Written by Investigator Wilkins.

During the exit conference, Mr. Cornwell asks which investigator cited observation number three. I, Investigator Wilkins, explain that I cited observations 3a and 3b. Investigator Medina states she cited observation 3c. Mr. Cornwell and the firm's lawyers, Mr. Jarcho and Mr. Pilot, express concern over the wording of the initial sentence of the observation and inquire if the sentence is structured from canned language taken from the software program we use. The attorneys request I

reword the initial statement. I explain that the statement, as worded, is accurate as the company has not executed the testing, completed the validation activities, or documented the validation results for the [redacted] and [redacted] program. I state the use of the systems and issues were reviewed with Mr. Shirley. I remind them that during the course of the inspection they were informed that a lack of a documented and completed validation for these two systems would be cited as an observation. Also, I explain that the observation, as worded, acknowledges they have a software validation plan and are in the process of planning validation activities.

Mr. Cornwell indicates he understands the observations for both 3a and 3b. Observations 3a and 3b were not annotated. Prior to discussing the individual observations, Mr. Cornwell states that he has decided not to annotate the FDA-483 observations because the annotation statements are too restrictive and limiting. Mr. Cornwell states the company's management will respond to all the observations in writing to the FDA.

Related Exhibits (Observations 3a and 3b):

The exhibits relevant and related to this observation include Exhibit #M1 through Exhibit #M8.

Reference: 21 CFR 820.70(i)

Relevance (Observations 3c):

FDA-483 ITEM NUMBER 3c: Written by Investigator Medina.
The [redacted], system, Version [redacted] has not been validated for its intended use. Exhibit L89 is the firm's current Software Validation Plan and Exhibit L90 is the [redacted]' dated [redacted]. Ben Shirley, Quality Manager, stated that these are the current software validation activities which are being conducted by the firm in association with the [redacted] software applications currently being utilized by the firm.

The firm's Software Validation Master Plan schedule, updated on [redacted] Exhibit L89, Page does not indicate the current status of the Test Protocol and designates the criticality for planning priority and planned completion date. The [redacted] modules which are currently planned to be validated are as follows:

DATAWORKS MODULE	PRIORITY	PLANNED COMPLETION DATE
Issuing "Work Orders" (Bill Of Operations, Bill Of Materials, maintaining	[redacted]	[redacted]

rework order procedures)		
Issuing NCMRs ("Quality Control")	[redacted]	[redacted]

During the inspectional close-out, Ben Shirley indicated that the firm is not utilizing the [redacted] modules as follows: [redacted]
Therefore, these modules were removed from the FDA-483 as this information was not provided to me during the course of this inspection, only during the inspectional close-out.

Discussion with management FDA-483 item number 3c:

c) Written by Investigator Medina. Mr. Shirley was not able to provide an updated Software Validation Plan schedule for completion at the time of this inspectional closeout.

Related exhibits (Observation 3c):
The exhibit relevant and related to this observation include the Exhibit as follows: L89.

OBSERVATION 4

The corrective and preventive procedures addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems were not defined.

Specifically, the Corrective and Preventive Action procedure, Document No. [redacted] Revision [redacted] Revision Date [redacted], does not define how data will be presented to the Materials Review Board (MRB), CAPA Committee, for effective analysis. For example:

a) The [redacted] MRB Review reports include data analysis on [redacted]. The procedure does not define how the failure codes are used by the company and what the failure codes represent in relation to data analysis of the CAPA and complaint handling systems.

1. As an example, 12 complaint records were documented for the electrodes not fitting into pencil, which was described as the same problem, but [redacted] different failure codes were used to document the type of failures in the complaint records. The Corrective Action Report (CAR) Number [redacted], Origination Date [redacted], identifies the complaint issues as the same for the complaint records.

2. Complaint [redacted] dated [redacted] for Electrical Surgical Unit [redacted]

was assigned failure code [redacted], however failure analysis revealed that the [redacted] Complaint [redacted] dated [redacted], for [redacted] was assigned failure code [redacted], however failure analysis also revealed that the unit had no sound because the [redacted]

b) The [redacted] MRB Review reports include data analysis on the [redacted] The procedure does not define how the number is obtained or what the number represents, such as the number is the actual number of hard copy complaint records, the actual number of devices/units alleged as defective by the complainant, the number of devices/units returned and tested, or number of complaints confirmed.

Reference: 21 CFR 820.100(a)(1)

Relevance (Observation 4a1):

FDA-483 ITEM NUMBER 4.a.1: Written by Investigator Wilkins.

On 02/03-07/04, 02/09-10/04, and 02/24-25/04, I, Investigator Wilkins, reviewed records and procedures maintained for the Corrective and Preventive Action Subsystem. The records reviewed included complaints, medical device reports (MDR's), non-conforming material reports (NCMR's), Corrective/Preventive Action Reports/Requests (CAR's), and Material Review Board (MRB) Quarterly Reports, refer to the subsection titled Corrective and Preventive Action Subsystem under the Manufacturing/Design section of the EIR.

A review of the Corrective and Preventive Action (CAPA) procedure, Document No [redacted] Revision [redacted] Revision Date [redacted] revealed that the procedure does not define how data will be presented to the Materials Review Board (MRB), CAPA Committee, for effective analysis. Section [redacted] of the Corrective and Preventive Action (CAPA) procedure assigns the responsibility of analyzing sources of quality data and identifying existing and potential product and quality problems to the MRB, which functions as the Corrective and Preventive Action Committee, refer to Exhibit #M9 Page 3.

Section [redacted] of the procedure instructs the Quality Assurance unit to collect data from sources such as

[redacted]

Section [redacted] of the procedure designates the Quality Assurance

unit as responsible for determining how to present the data for effective analysis, but the procedure does not provide instruction on how to collect the data, define what the data represents, or describe how the data will be analyzed and presented to the MRB for review, refer to Exhibit #M9 Page ⟷

A review of the MRB Review reports revealed that the reports include data analysis of the

The report titled Review of the Utah Medical Quality System includes the following reports sorted by

The report titled MRB Review on includes the following reports sorted by

The report titled MRB Review on includes the following reports sorted by

The report titled MRB Meeting Minutes includes the following reports sorted by

Prior to the review of the complaint records, the following complaint related procedures were reviewed:

- Customer Complaint System, Document No. [redacted], Revision [redacted], Revision Date [redacted], refer to Exhibit #M26
- Customer Complaint Investigation, Document No. [redacted] Revision [redacted] Revision Date [redacted] refer to Exhibit #M27
- Post Distribution Monitoring, Document [redacted] Revision [redacted], Revision Date [redacted], refer to Exhibit #M28

A review of the complaint related procedures revealed that the firm has not defined, in these procedures or the CAPA procedure, how the failure codes will be used or what the failure codes represent in relation to data analysis of the CAPA and complaint handling systems.

During the review of complaint records, I requested a list of the failure codes assigned after an investigation is performed. Mr. Shirley provided a list of the failure codes and failure code descriptions, refer to Exhibit #M13. A review of complaint records revealed that the firm assigns the failure codes after an investigation is completed and is inconsistent in the assignment of the failure codes. As an example, [redacted] complaint records were documented for the "electrodes not fitting into pencil". The information included with the complaint records documents the problem or issue was the same for all [redacted] of the complaints, but [redacted] different failure codes were used to document the type of failures in the complaint records. The complaint records and the failure codes assigned per complaint for the electrodes not fitting into the pencil are as follows:

Complaint #	Failure Code Description	Failure Code	Exhibit #

Complaint #	Failure Code Description	Failure Code	Exhibit #

Even though the failure code assignment was inconsistent, the company was able to identify it as a quality issue and initiated a Corrective Action Report/Request (CAR) Number —, Origination Date ——, which identifies the complaint issues as the same for the complaint records, refer to Exhibit #M29. The complaints and lot numbers associated with Corrective Action — are identified in the corrective action file, refer to Exhibit #M29 Page

On 02/24/04, I reviewed the complaints, including those identified above, with Mr. Cornwell, President and CEO. I stated to Mr. Cornwell that a review of the complaints identified that they are inconsistent in the assignment of failure codes and that the use of the failure codes is not defined in any of the procedures. In response, Mr. Cornwell stated they do not use the failure codes as a means to initiate an investigation or a corrective and preventive action. When asked for the purpose of the failure codes, Mr. Cornwell stated they do not use the failure codes for anything. In response, I stated the company uses the failure code data in several data analysis reports that are sorted by failure code in the MRB ——— reports, refer to Exhibit #10, Exhibit #11, Exhibit #12 and Exhibit #5. Mr. Cornwell then explained that the reports sorted by failure codes are only used to obtain an immediate impression of the big picture and that each complaint hard copy file is reviewed individually to determine if there is a need for an investigation and/or corrective action.

I explained that the purpose and use of the failure codes must be defined in the procedures if the company is going to use the data in reports for data analysis provided to the MRB. I explained that since the MRB is responsible for analyzing sources of quality data to identify existing and potential product and quality problems, the data must provide meaningful and accurate information for the MRB to base its decisions. Mr. Cornwell stated the MRB uses a variety of data to make their decisions. Mr. Cornwell and ——— stated the company is in the process of reviewing the application of the failure codes and better defining the use of the failure codes.

In summary, the Corrective and Preventive Action (CAPA) procedure, Document No. ——— Revision — Revision Date ——— and related procedures do not define how the failure codes are used by the company and what the failure codes represent in relation to data analysis of the CAPA and complaint handling systems presented to the MRB.

Discussion with Management (Observation 4a1):

Written by Investigator Wilkins.

During the exit conference, Mr. Cornwell expresses concern with the first sentence of the observation and states it is not balanced. The company's lawyers ask if the sentence was taken as canned language from the FDA software program. I explain that the first sentence was selected from the software program, but that it is accurate in that the company has not defined certain elements of the CAPA data analysis in their procedure. I also state that the issue was discussed with Mr. Cornwell and [redacted]. Mr. Cornwell acknowledges discussing the issue with me. Mr. Cornwell states he understands the observation, but has an issue with the canned language of the software program. Mr. Pilot states that as the company's attorney, he has a problem with the wording taken from the Turbo EIR software program because the issues are not clear and the sentences are all inclusive making the issue seem worse than what it may actually be. Mr. Pilot requests that their position and concerns related to the Turbo software program be documented and relayed to the FDA management staff.

Mr. Cornwell states he understands the issue as I had reviewed the complaint records and discussed the issues with him.

Related Exhibits (Observation 4a1):

The exhibits relevant and related to this observation include Exhibit #M5 and Exhibit #M9 through Exhibit #M29.

Reference: 21 CFR 820.100(a)(1)

Relevance (Observation 4a2):

FDA-483 ITEM NUMBER 4.a.2: Written by Investigator Jerndal.

A review of [redacted] Electrical Surgical Unit (ESU) device complaints revealed [redacted] incidence where an identified failure mode was described but not coded.

Complaint [redacted], receipt date [redacted], is attached as Exhibit R116. The failure code [redacted], is found on Page [redacted] Under the heading, Investigation Findings, at the bottom of Page [redacted] it states, [redacted] "

Complaint receipt date is attached as Exhibit R102. Page failure code cites, However, at the bottom of Page it states, under results,

Related Exhibit (Observation 4a2):

The exhibits relevant and related to this observation include the Exhibits as follows: R102 and R116.

Reference: 21 CFR 820.100(a)(1)

Relevance (Observation 4b):

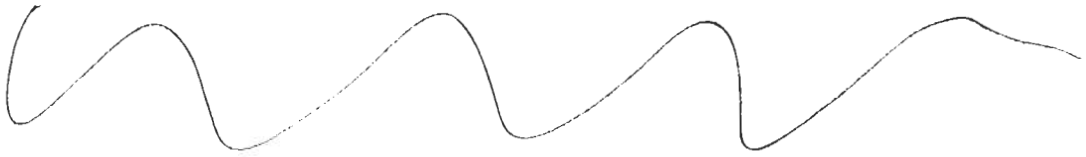
FDA-483 ITEM NUMBER 4b: Written by Investigator Wilkins.

For a discussion related to this observation, refer to the relevance section of observation 4a1. A review of the MRB Review reports revealed that the reports include data analysis on the number of Complaints

The report titled Review of the Utah Medical Quality System includes the following reports sorted by

The report titled nd MRB Review on includes the following reports sorted by

The report titled MRB Review on includes the following reports sorted by



The report titled [redacted] MRB Meeting Minutes includes the following reports sorted by

The Corrective and Preventive Action (CAPA) procedure, Document No. [redacted], Revision [redacted] Revision Date [redacted], does not define how the number of complaints is obtained or what the number represents, such as the number is the actual number of hard copy complaint records, the actual number of devices/units alleged as defective by the complainant, the number of devices/units returned and tested, or number of complaints confirmed, refer to Exhibit #M9. Similarly, the related procedures such as the Customer Complaint System, Customer Complaint Investigation, and Post Distribution Monitoring, do not define how the number of complaints is obtained or what the number represents, such as the number is the actual number of hard copy complaint records, the actual number of devices/units alleged as defective by the complainant, the number of devices/units returned and tested, or number of complaints confirmed, refer to Exhibit #M26, Exhibit #M27, and Exhibit #M28, respectively.

As an example, [redacted] complaint records were documented for the ESU Sterile Accessories for an issue described as the "electrodes not fitting into pencil". The information documented in these complaint records indicate that at least [redacted] electrosurgical pencil devices, Part [redacted], were reported as electrodes not fitting into the pencil, refer to Exhibit #M14 through Exhibit #M25. These [redacted] complaints were received during the period between [redacted] through [redacted] The Complaints By [redacted] Complaints data analysis report included in the [redacted] MRB Review report, indicates that a total of [redacted] complaints were recorded in all of 2003 for all the ESU Sterile Accessories product family, including the ESU-305 devices, refer to Exhibit #M5 Page [redacted] The Corrective Action Report/Request [redacted] documents that these [redacted] complaints included [redacted] devices reported as defective, [redacted] were returned to the company, and [redacted] were confirmed as defective, refer to Exhibit #M29 Page [redacted]

As stated previously, the Corrective and Preventive Action (CAPA) procedure, Document No. [redacted] and other related procedures do not define how the number of complaints is obtained or what the number represents for the Complaints By [redacted] report submitted with the MRB Reports, such as whether the number is the actual number of hard copy complaint records,

the actual number of devices/units alleged as defective by the complainant, the number of devices/units returned and tested, or number of complaints confirmed. Since the MRB ——— Reports are used by the MRB to identify product or quality issues, the number of complaints may be under represented as the approximate number reported as defective was — but the complaint numbers for all ESU Sterile Accessories Product Family reported in the ——— reports totaled only— for .— .

On 02/24/04, I reviewed the complaints, including those identified above, with Mr. Cornwell, President and CEO. I stated to Mr. Cornwell that a review of the complaint records identified that there were more devices alleged as having problems or issues than were reported in any of the MRB quarterly data analysis reports. Mr. Cornwell stated that just because a customer states the devices have a problem does not mean that it is a problem or that the complaint is confirmed. As an example, I explained that the issue documented in the —complaint records reporting that the electrodes did not fit into the pencils was confirmed as a problem by the company, but yet they did not include the number of devices affected in the confirmed defective category if the units were not returned for testing. In addition, the MRB ——— reports do not include all of the information for comparison such as Number Reported Defective, Number Returned, Number Evaluated/Tested, and Number Confirmed Defective.

Mr. Cornwell explained the process on how complaint records and data analysis is performed on the complaints. He stated that the hard copy complaint records are pulled and reviewed individually and that a Summary of Complaint Evaluations report is created by the Complaint Coordinator from the information obtained from the hard copy complaint files received for that week. Mr. Cornwell stated he reviews the report with his staff to identify any possible trends or issues. Mr. Cornwell offered to provide the reports generated for 2003. I stated the reports, if provided, would be reviewed.

On 02/25/04, Mr. Cornwell provided the Summary of Complaint Evaluations for the period including ——— to ——— , refer to Exhibit #M30. Mr. Cornwell stated he was providing all the Summary Complaint Evaluation reports generated after the date of the previous inspection conducted by FDA. I stated the Summary of Complaint Evaluation reports would be evaluated and considered for the issue raised concerning the what the number of complaints represents in the data analysis reports generated by the company.

A review of the complaint files and the Summary of Complaint Evaluations demonstrates that the company does review, evaluate and investigate individual complaint records, but the information in these Summary of Complaint Evaluation reports do not provide the same information as included in the MRB Quarterly Reports. I explained to Mr. Cornwell that the definition of a complaint means that a complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. I explained that the definition defines a complaint as an "alleged" deficiency not a "confirmed" deficiency. I explained to Mr. Cornwell that complaints may not be confirmed initially or that just because a product is not returned for evaluation does not mean that it

was not a complaint. Mr. Cornwell stated that nurses and hospital staff are motivated to return the product for evaluation because his company will provide credit or additional product in exchange for the returned device. Mr. Cornwell states that if the product is not returned then they cannot confirm the complaint and should not have to include all the units identified by the complainants unless they can be confirmed with an evaluation of returned product. He feels that when there is a true problem with the device, the hospital staff always return the product. I explained that there are many instances where the product is not returned, but the lack of return of an alleged defective product does not remove the obligation from the company of reporting or capturing the number of units/devices alleged in the data analysis reports.

Mr. Cornwell stated that he has initiated corrective actions based on as few as one complaint and that they are diligent in initiating corrective actions when they are warranted. I state that the issue is not that they have not initiated a corrective action, but on the representation of the data and numbers for the data analysis performed for the MRB ——— Reports and Management Reviews.

In summary, the Corrective and Preventive Action (CAPA) procedure, Document No. ——— and other related procedures do not define how the number of complaints is obtained or what the number represents for the Complaints By ———report submitted with the MRB ——— Reports, such as whether the number is the actual number of hard copy complaint records, the actual number of devices/units alleged as defective by the complainant, the number of devices/units returned and tested, or number of complaints confirmed through evaluation and/or investigation. I explained to Mr. Cornwell that the data submitted for the MRB ——— Reports should be representative of the actual data such as including the number of alleged defective devices/units along with reporting the number of hard copy complaints and any other information they deem relevant.

Discussion with Management (Observation 4b):

During the exit conference, I state the issue raised pertains to the lack of defining in their procedures what the numbers included in the reports represent. Mr. Cornwell stated he understood the issue.

Related Exhibits (Observation 4b):

The exhibits relevant and related to this observation include Exhibit #M5 and Exhibit #M9 through Exhibit #M29.

OBSERVATION 5

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.

Corrective/Preventive Action Request, CAR NO.: —, was opened —, closed — and affectivity verified on — and —, concerning the — The MRB CAPA meeting minutes and CAR— file, does not document the product lot numbers involved with this defect, and does not document the rationale for releasing these lots for distribution.

Reference: 21 CFR 820.100(a)(3)

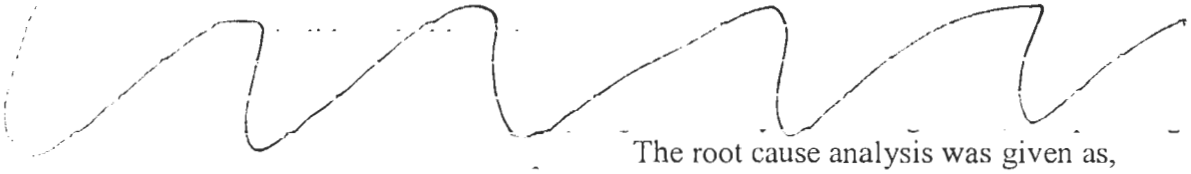
Relevance/ Additional details of the observation:

Discussion with management:

FDA-483 ITEM NUMBER 5: Written by Investigator Jerndal.

CAR 858

On Wednesday, 2/4/04, Ben Shirley supplied me with a copy of Corrective/Preventive Action Request CAR —originator date — ', attached here as Exhibit R70. This CAR states, —



The root cause analysis was given as, — The — cited complaints plus — additional received since this CAR was opened are submitted here as follows:

This car was closed —, and affectivity verification was done —, noting, —

The corrective action was implemented via — change proposals. The —, Exhibit R75, CP —dated entered — This change involved — from Revision — to Revision — adding an — and changing — to read. — versus

in the old revision. Operators were also retrained. This is not discussed in the above CP but is noted on the Corrective Action document. The training record for this is attached as Exhibit R76.

The change proposal attached here as Exhibit R77, CP , date entered , notes as description of change, And reason for the change, The bonding procedure, was revised to the new and current Revision The detailed changes to the attached marked-up copy are found under Sections and Employees were retrained, and the training record is attached as Exhibit R78.

Mr. Shirley explained that upon review of the process, it was found that a new employee in manufacturing was not properly following process expectations. A review of the process procedure revealed that detail was missing from the description of Mr. Shirley's description of the redline changes to the procedure, introduced with Exhibit R77 above, was that they were clarifications of the process to bring it back in line with the intent of the original qualification. Exhibit R79 is the current manufacturing procedure revision , dated This scenario, as described by Mr. Shirley, is not clearly characterized in the CAR documentation. I asked Mr. Shirley to supply me with documentation supporting the validation for this bonding operation.

On Saturday, 2/07/04, Mr. Shirley informed me that they could not find the qualification for this bonding process. He stated that the manufacturing personnel had relied on memory when re-establishing the procedure changes initiated in the update to Revision for that manufacturing procedure.

On Tuesday, 2/10/04, Mr. Shirley supplied me with a copy of Test Report Revision dated , attached here as Exhibit R80. I asked Mr. Shirley if this applies to the bonding operation, subject of CAR . He said yes, part of it did. I told Mr. Shirley that I had asked for any validation or qualification of the bonding process described in CAR times already, and that each time, he had responded that he either couldn't find it or that they did not have any qualification or validation for this bonding process. I asked him why this suddenly appeared six days after my first request. He replied that he thought I was referring to the degree rocking jig/process portion of this bonding specifically and only. I reiterated that I had asked for any and all information supporting this process. He stated that that was difficult as that information has "many fingers into their documentation history" sometimes going back many years. I replied that if they are no longer able to produce these documents without great effort, that they may no longer have continuity with the currently used process.

A reviewed this test report revealed a reference to Test Report , revision dated Exhibit R82, and Test Protocol revision dated

- Exhibit R81. These two documents appear to contain information supporting qualification work done on the subject of the CAR. Mr. Shirley did not supply these documents in response to my requests for validation supporting that bonding operation. They were only supplied after I specifically requested them after I observed their reference in the one document he did supply, Test Report

The bonding assembly as described in , Exhibit R79, is illustrated by a drawing on page . The parts illustrated in this assembly are all mounted into a locking jig as described on page Section The adhesive is applied by an operator, by hand, using the adhesive dispenser described in Section page The adhesive is applied per the drawing on page and the description on page The glued assembly still in the jig is placed under the The jig bottom is angled so that the part rests at degrees to the overhead exposure. After a cure time of at one angle, the jig is tipped to the other direction to expose the other side of the assembly to This is all done manually. Test Report Exhibit R80, summarizes the various sample sets and test conditions subjected to visual, leak, and destructive (pull testing) analysis. We reviewed the raw data and matched it against the test result summary in this report. We also verified the work orders and exposure history records summarized in Section page of the Test Report.

This test report references the Test Protocol , Exhibit R81, and additional Test Report ; Exhibit R82. summarizes testing done to qualify solvent bonding of tubing into the stop cock pockets of the assembly illustrated in page drawing of the Exhibit R79, procedure. This bonding assembly is a manual solvent bond process using per the procedure , Exhibit R55. I requested the raw data supporting the Test Report on Monday, 3/01 and again on Tuesday, 3/02, however, Mr. Shirley had not produced this request by the end of the inspection.

Exhibit R83 is a list of DELTRAN 902-586 assemblies completed through . The lot numbers identified from the complaint failures (Exhibits R71 through R74) include Lot # (Work Order #) , dated and Work Order , dated The final corrective action culminating in employee retraining was completed . This then exposed additional lot numbers to conditions of this failure mode, that is, Lot dated , and dated I reviewed these work orders and the work order number completed prior to the initial manifestation of this failure mode. That prior work order is dated I also confirmed that this work order was processed according to the older assembly, prior to introduction of the new stock cock and base plate assembly, subject of changes resulting in the bond qualification testing discussed above, Exhibits R80 through R82. This bond failure issue, subject of CAR , is apparently co-incident with the introduction of the new assembly. Exhibit R84 is Change Procedure, CP number , approval date that introduces the into the DELTRAN production. The Device History Records for the DELTRAN lots affected by this bond failure are attached as follows:

- Exhibit R85 -

I asked Mr. Shirley for any documentation surrounding this CAR — where they had identified the affected product lots and ascribed disposition of affected lots. I also specifically requested any documentation concerning this Correction Action — that may be found in the proceedings of the Material Review Board's (MRB) periodic corrective action/preventive action meetings. —— —— supplied copies of two references from the MRB meeting of ——— , characterizing them as the only documentation in the MRB proceedings relating to CAR —— These are submitted here as Exhibit R89.

Mr. Shirley supplied me with an update to CAR — , attached here as Exhibit R90. This CAR page adds the additional affectivity verification, ———

In addition, there is an attached memo to the MRB from ——— subject: CAR — dated — In this memo it is stated that, ——— ——— " And in the last paragraph,

Mr. Shirley verified that ' is not a part of the MRB board and that the information in this memo would be submitted to the MRB formally at their next meeting. Exhibit R91 is a copy of the Label Specification —— revision — dated ——— ——— Exhibit R92 is a copy of, ' ——— ——— ———

Discussion with management FDA-483 item number 5:
The exhibits relevant and related to this observation include the Exhibits R89 through R92.

OBSERVATION 6

Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been defined.

For example, the Customer Complaint Investigation procedure, Document No. — ——— Revision — Revision Date ——— does not define the process of how the recent complaint history is evaluated and/or does not require the recording, in the individual complaint file, of how the recent complaint history and/or service history was evaluated for that particular

complaint. For example:

a) **— complaint records, received since ———; were reviewed and the documentation in the complaint records did not include the information of how the recent complaint history was evaluated or performed.**

1. **Complaint Number ———, Received Date ———, documents that the complaint history for the past ——— was searched and no similar incidents were found. The procedure does not describe the process of a complaint history search. The complaint record, Number ———, does not document how the complaint history was searched, such as searching in ——— by generating a report by product; using a report generated from ——— to aid in the identification of hard copy complaint files and manually reading each complaint description; using the MRB ——— Reports data generated every ——— or pulling and reading of all hardcopy complaint files without the aid of a complaint list generated from ———**

2. **Complaint Number ——— Received Date ——— documents that the complaint history for the past ——— revealed —ccurrences of bent loops found. The procedure does not describe the process of a complaint history search. The complaint record, Number ———, does not document how the complaint history was searched, such as searching in ——— by generating a report by product; using a report generated from ——— to aid in the identification of hard copy complaint files and manually reading each complaint description contained in the hard copy files; using the MRB ——— Reports data generated every ——— or pulling and reading of all hardcopy complaint files without the aid of a complaint list generated from ———. Also, the procedure and/or complaint record do not document or define what the —— occurrences represent, such as whether the number represents hard copy complaint records; number of units/devices allegedly reported by the complainant in all the complaint records searched; number of units/devices returned and tested; and/or number of confirmed units/devices defective or confirmed problems.**

b) **A review of —ustomer complaint records received since ——— for the FINESSE Electrical Surgical System device noted — different described scenarios for ——— look back reviews, including —complaints where there is no indication that a look back was done as part of the complaint investigation. The— look back descriptions are noted below followed by the total number of complaints where each was observed as follows:**

Reference: 21 CFR 820.198(a)

Relevance (Observation 6a1 and 6a2):

FDA-483 ITEM NUMBER 6.a.1/6.a.2: Written by Investigator Wilkins.

During the review of the CAPA Subsystem, the complaint procedures and complaint records were reviewed during the period including [redacted] and [redacted]. The following complaint procedures were reviewed:

- Customer Complaint System procedure, Document [redacted], Revision [redacted] Revision Date [redacted], refer to Exhibit #M26
- Customer Complaint Investigation procedure, Document [redacted], Revision [redacted] Revision Date [redacted], refer to Exhibit #M27
- Post Distribution Monitoring procedure, Document No. [redacted], Revision [redacted] Revision Date [redacted] refer to Exhibit #M28

The Customer Complaint Investigation procedure, Document No. [redacted], Revision [redacted] Revision Date [redacted] does not define the process of how the recent complaint history is evaluated and/or does not require the recording, in the individual complaint file, of how the recent complaint history and/or service history was evaluated for that particular complaint, refer to Exhibit #M27. Section [redacted] of the procedure only instructs as follows:

[redacted], refer to Exhibit #M27 Page

Similarly, section [redacted] of the Customer Complaint System procedure, Document No. [redacted] Revision [redacted] Revision Date [redacted], only instructs to review the lot and complaint history as required, but the procedure does not define the process of how the recent complaint history is evaluated and/or does not require the recording, in the individual complaint file, of how the recent complaint history and/or service history was evaluated for that particular complaint, refer to Exhibit #M26 Page [redacted]

[redacted] complaint records, received during the period including [redacted] to [redacted] were reviewed and the documentation in the [redacted] complaint records did not include the information of how the recent complaint history was evaluated or performed. As an example, Complaint Number [redacted] Received Date [redacted] documents that the complaint history for the past [redacted], was searched

and no similar incidents were found, refer to Exhibit #M4 Page [redacted] The procedures do not describe the process of a complaint history search, refer to Exhibit #M27 and Exhibit M#26. The complaint record, Number [redacted] does not document how the complaint history was searched, such as searching in [redacted] by generating a report by product; using a report generated from [redacted] to aid in the identification of hard copy complaint files and manually reading each complaint description; using the MRB [redacted] Reports data generated every [redacted] or pulling and reading of all hardcopy complaint files without the aid of a complaint list generated from [redacted], refer to Exhibit #M4.

As another example, Complaint Number [redacted] Received Date [redacted], documents that the complaint history for the past [redacted] revealed [redacted] occurrences of bent loops found out of [redacted] loop electrode devices shipped over the same period, refer to Exhibit #M31 Page [redacted] The procedures do not describe the process of a complaint history search, refer to Exhibit #M27 and Exhibit #M26. The complaint record, Number [redacted] does not document how the complaint history was searched, such as searching in [redacted] by generating a report by product; using a report generated from [redacted] to aid in the identification of hard copy complaint files and manually reading each complaint description contained in the hard copy files; using the MRB [redacted] Reports data generated every [redacted] or pulling and reading of all hardcopy complaint files without the aid of a complaint list generated from [redacted] refer to Exhibit #M31.

In addition, the procedures and/or complaint record do not document or define what the occurrences represent, such as whether the number represents hard copy complaint records; number of units/devices allegedly reported by the complainant in all the complaint records searched; number of units/devices returned and tested; and/or number of confirmed units/devices defective or confirmed problems.

Discussion with Management (Observation 6a1 and 6a2):

During the exit conference, Mr. Cornwell states that he was aware of the observation and understood the issue as he was part of the discussion. He acknowledged the complaints were reviewed with him.

Related Exhibits (Observation 6a1 and 6a2):

The exhibits relevant and related to this observation include Exhibit #M4, Exhibit #M26 through Exhibit #M28, and Exhibit #M31.

Reference: 21 CFR 820.198(a)

Relevance (Observation 6b):

FDA-483 ITEM NUMBER 6b: Written by Investigator Jerndal.

Following is a listing of the complaint files reviewed and grouped by look-back determination as documented in the file. That reference is generally found under the section "Complaint Summary" on page [redacted] of the complaint form, but occasionally referenced elsewhere. Exhibit numbers are referenced for the example's copied. A second review of notes and copies change some of the totals for some of the groupings cited.

No Look-back Documented

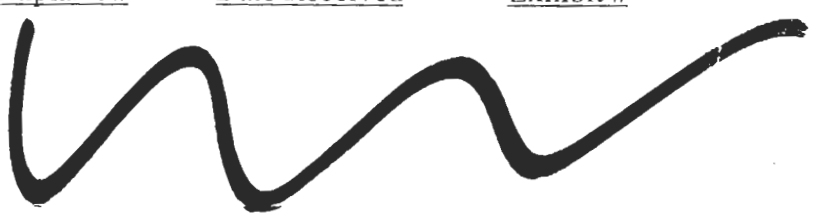
Complaint #	Date Received	Exhibit #

3-year Complaint & Service Look-back Documented

Complaint #	Date Received	Exhibit #

Complaint History Look-back Only Documented

Complaint #	Date Received	Exhibit #



Service History Look-back Only

Complaint # Date Received Exhibit #

Look-back Documented in Customer Letter Only

Complaint # Date Received Exhibit #

Look-back Time Unspecified

Complaint # Date Received Exhibit #

Complaint & Service History Look-back for Unit Only Documented

Complaint # Date Received Exhibit #

Exhibits (Observation 6b):

The exhibits relevant and related to this observation include the Exhibits as follows: R100 through R118.

OBSERVATION 7

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

A review of [redacted] work orders (device history records), manufactured after [redacted], revealed the following [redacted] errors that were not detected during the review and approval of the device history records.

a) The following error was not detected during review and approval of Device History

Record: Extrusion molding batch, product test samples for work order [redacted] Assembly [redacted], were selected by production personnel according to an obsolete sample scheme.

b) **The time [redacted] was put into the dryer was not recorded on the bill of operations .(BOO) for Assembly [redacted] work order [redacted] as required by this BOO. This is done to establish conformance with the minimum drying time of [redacted] specified for this polymer.**

Reference: 21 CFR 820.184(d)
Relevance/ Additional details of the observation:

FDA-483 ITEM NUMBER 7a: Written by Investigator Jerndal.
The Work order cited here is attached as Exhibit R5. The copy of the "QUALITY ASSURANCE INSPECTION REPORT", reveals that quality control samples were taken at [redacted] and [redacted] am on 2/18/04. (This record does not document the planned sample frequency.) Note that the work order cited in the 483 is not the one discussed with Mr. Shirley for this observation. This Work Order [redacted] also utilized a sampling frequency of [redacted], however, that sampling scheme may still be specified for this particular part. Work order, [redacted], start date [redacted] for the extruded product Assembly [redacted] Tubing, UMP Extruded, attached here as Exhibit R3. Pages [redacted] show the Attribute Inspection Form, noting the sampling interval of [redacted] These sample result records reveal an actual sampling interval of [redacted] I pointed this out to Mr. Shirley. A Request for Deviation/Waiver [redacted] was then initiated. The batch was subsequently released with justification as stated on line [redacted] of the waiver, page [redacted] of Exhibit R3. The sample interval for this Part [redacted] was recently changed from [redacted] units every [redacted] to [redacted] unit [redacted] This incident may be an isolated oversight on the part of the process operators. This oversight was not caught by subsequent Device History Record review and release.

FDA-483 ITEM NUMBER 7b: Written by Investigator Jerndal.
The same work order cited above, Exhibit R3, page [redacted] is the Bill of Operations. On line [redacted] the requirement is to record the time, signature and date when resin material is first put into the dryer hopper. This block is not completed for this work order. This was brought to Mr. Shirley's attention. His later response was that it appears to be an oversight on the part of the operators. This oversight was not caught by subsequent Device History Record review and release.

Exhibits:
The exhibits relevant and related to this observation include the Exhibits R3 and R5.

REFUSALS

Written by Investigator Medina.

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Written by Investigator Medina.

On 3/3/04, a FDA-483, Inspectional Observations, was issued to Kevin L. Cornwell, CEO/Chairman, in the presence of Mr. Shirley. Mr. Cornwell also had individuals connected via telephone as follows: Larry Pilot, Attorney; Dan Jarcho, Attorney; and [redacted] FDA Investigators Medina, Wilkins, and Jerndal were also present.

The close-out meeting was audio taped in its entirety and the tapes are included as Exhibits L1. The tapes are contained with the original EIR only. Mr. Cornwell stated that he did not wish to have the FDA-483 annotated and he did not promise to correct the observations made on the FDA-483. The Investigator responsible for each observation has provided the supporting text and documentation and the author of each item is noted within the Objectionable Conditions section of this report.

ADDITIONAL INFORMATION

Written by Investigator Medina.

Sterile products are processed utilizing [redacted] sterilization contracted by the firm to be performed at [redacted] located in [redacted] is under contract with UTMD to act as the firm's Microbiologist. [redacted] provides opinion on sterilization issues including bioburden testing, sterilization validation, comparative resistance testing, packaging validation, and shelf-life studies. He was present on 2/12/04 and provided answers to Investigator Wilkin's questions associated with [redacted] sterilization of the firm's products. Additionally, [redacted] performs laboratory testing in the aforementioned areas.

VOLUNTARY CORRECTIONS

Written by Investigator Medina.

Exhibit L10 is the firm's response to the previous FDA-483 (dated 3/12/03) which was drafted, compiled, and provided to the current Investigator team during the current EI on 2/23/04. Exhibit L10a is the firm's cover letter dated 4/11/03 sent to the FDA Denver District Office from Mr. Cornwell in response to the above mentioned FDA-483.

During the previous inspection dated 2/24-3/12/03, an FDA-483, Inspectional Observations, was issued to the management of the firm. These items were again covered during the current inspection to determine what compliance initiatives were made in association with these cGMP/Quality Systems Regulation deficiencies. A discussion of the previous FDA-483 items (found in **bold face type**) and the corrections, partial corrections, or lack of corrections of these items are found as follows:

Observations listed on form FDA 483 for Utah Medical Products Inc. EI dated 2/24-3/12/03 et al.

OBSERVATION 1: Investigators Medina (D.2), Wilkins (A, B, C, E), and Jerndal (D.1, F) followed up on this observation.

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately and fully validated and approved according to established procedures.
Specifically,

A. <u>Regarding Comparative Resistance Studies for IUP and Deltran devices:</u>

1. [redacted] comparative resistance studies reviewed for the IUP product line and Deltran product line from [redacted] form the basis for supporting the use of Master Product BI's or Process Challenge Devices for the current [redacted] sterilization validation. The following are examples of where they are inadequate:

DATE	Device	Lab Study #	Comments

CORRECTION:

Written by Investigator Wilkins.

On the dates including 02/10-12/04, 02/17/04, and 02/23-25/04, I, Investigator Wilkins, reviewed records related to the sterilization process in order to assess the issues related to this observation. I reviewed all the records related to the sterilization validations, annual sterilization assessments, comparative resistance studies, environmental monitoring, and DHR sterilization cycle records, refer to the Production & Process Controls Subsystem subsection under the Manufacturing/Design section.

The company has conducted approximately [redacted] Comparative Resistance studies for the purpose of demonstrating that the process challenge device (PCD or Master Product) is more difficult to sterilize than the devices manufactured by the company, refer to Exhibit #M32. The company validated the [redacted] sterilization process in [redacted] with the use of product and process challenge devices (PCD's) in the sterilization validation cycle runs. The process challenge device, used in the validation, was selected based on the results of Comparative Resistance Study

[redacted] The comparative resistance studies conducted prior to [redacted] were for different PCD's used prior to the [redacted] sterilization process validation, and are no longer relevant to the current sterilization validation.

I requested and obtained, from [redacted], all the [redacted] Comparative Resistance Study Protocols related to this observation. [redacted] provided the following protocols:

Utah Medical Products provided all the Final Reports for the [redacted] Comparative Resistance Studies related to this observation, which included the following:

An observation pertaining to the Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted], was cited due to the selection of the inoculation sites on the device. The observation identified the following:

[redacted]

[redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted] Date [redacted] and Final Report [redacted] Comparative Resistance Study Laboratory No. [redacted] Report Date, [redacted], refer to Exhibit #M33 and Exhibit #M34, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted] is no longer applicable to the current [redacted] sterilization validation. The PCD (Master Product) in this study was a [redacted] syringe. Currently, the company uses a [redacted] syringe as the PCD, which was initially evaluated in early [redacted] for use in the sterilization validation.

In addition, I met with [redacted] to discuss the comparative resistance study. [redacted] provides contract laboratory and consultant services, to Utah Medical Products, on issues related to the sterilization process. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the devices included in Comparative Resistance Study Laboratory No. [redacted] This issue is resolved as the study is no longer applicable to the current sterilization validation. As additional information, [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites.

Similarly, an observation pertaining to the Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted] was cited due to the selection of the inoculation sites on the device. The observation identified the following:

[redacted]

I reviewed the [redacted] Comparative Resistance Study, Protocol No. [redacted], Date [redacted] and Final Report [redacted] Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted] refer to Exhibit #M35 and Exhibit #M36, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted] is no longer applicable to the current [redacted] sterilization validation. The PCD (Master Product) in this study was a [redacted] device. Currently, the company uses a [redacted] syringe as the PCD, which was initially evaluated in early [redacted] for use in the sterilization validation.

In addition, I met with [redacted] to discuss the comparative resistance study. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the devices included in Comparative Resistance Study Laboratory No. [redacted] This issue is resolved as the study is no longer applicable to the current sterilization validation. As additional information, [redacted] was able to demonstrate and provide the rationale

for the selected inoculation sites.

An observation pertaining to the Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted], was cited due to the selection of the inoculation sites on the device. The observation identified the following:

[redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted], Date [redacted], and Final Report [redacted] Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted] refer to Exhibit #M37 and Exhibit #M38, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted], is no longer applicable to the current [redacted] sterilization validation. The PCD (Master Product) in this study was a [redacted] syringe. Currently, the company uses [redacted] syringe as the PCD, which was initially evaluated in early [redacted] for use in the sterilization validation.

In addition, I met with [redacted] to discuss the comparative resistance study. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the devices included in Comparative Resistance Study Laboratory No. [redacted] This issue is resolved as the study is no longer applicable to the current sterilization validation. As additional information, [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites.

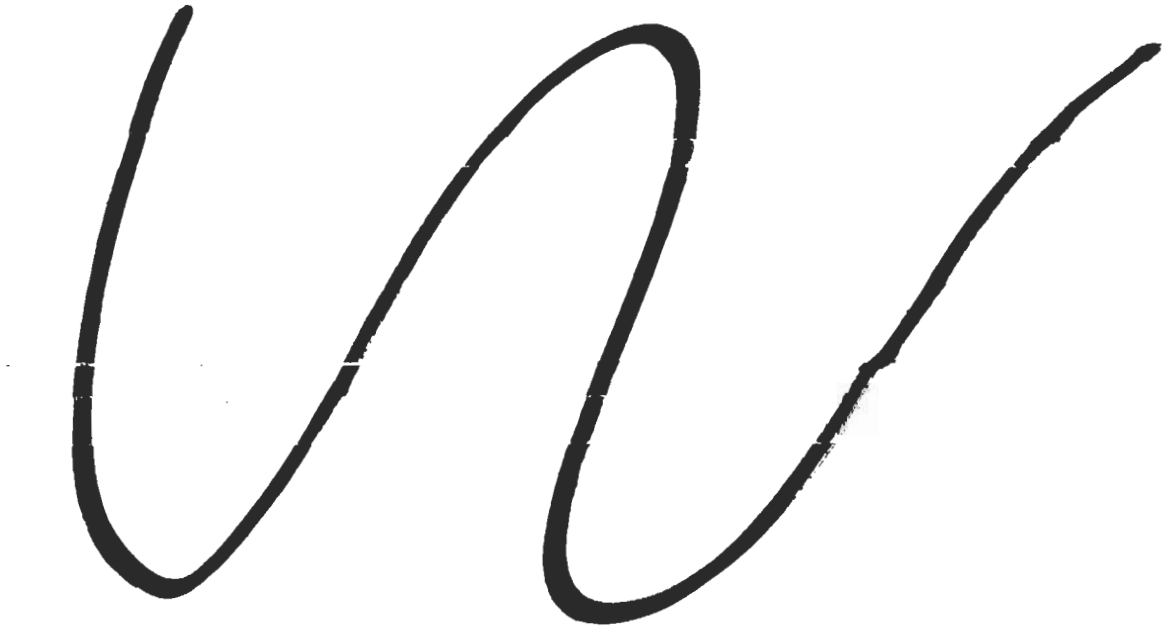
Another observation pertaining to the Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted], was cited due to the selection of the inoculation sites on the device and the device is no longer manufactured. The observation identified the following:

[redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted] Date [redacted] and Final Report [redacted] Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted] refer to Exhibit #M39 and Exhibit #M40, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted] was conducted to compare several PCD's (Master Products) to the most difficult to sterilize device manufactured by the company. The purpose was to select one or more PCD's to use for the sterilization validation and routine process monitoring. The study was conducted by comparing four PCD's, including [redacted] syringes, to the [redacted] Syringe w/sheath. The observation correctly identifies that the [redacted]

[redacted] is no longer manufactured, but the device is very similar to the [redacted] currently manufactured, refer to Exhibit #M45 Page 7.

The study describes [redacted]



Prior to meeting with [redacted] I reviewed the products currently manufactured by the company. [redacted], and Mr. Shirley, provided an overview of the products and answered questions pertaining to the manufacture, design and assembly of the products. On 02/12/04, I met with [redacted] to discuss the comparative resistance study. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the [redacted] devices included in Comparative Resistance Study Laboratory No. [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites. This issue is resolved as the study demonstrates the PCD is more difficult to sterilize than the device. This [redacted] device model is similar in design to the [redacted] and other [redacted] devices currently manufactured by the company.

Also, [redacted] explained that the [redacted] were not calculated for some of the comparative resistance studies as it is a reference point that is theoretical as the studies are conducted in [redacted] to get direct comparisons between the devices and PCD's. He stated the [redacted] provide a general reference point, but the information of value is the data, or time in minutes, that demonstrate either growth or no growth. He stated the device in question should be less resistant to sterilization than the PCD, which is demonstrated by the results of the data. [redacted] brought the data and results of all the comparative resistance studies and offered to calculate the [redacted] of any that were not calculated. On this particular day, I did not request [redacted] calculate the [redacted], but

did request them for a later date.

On 02/26/04, Mr. Shirley provided a document from [redacted] dated [redacted], which included the [redacted] for the comparative resistance studies we reviewed that were lacking the calculation, refer to Exhibit #M46. The [redacted] for Comparative Resistance Study Laboratory Report No. [redacted] demonstrate the that the most resistant areas of the [redacted] devices had a [redacted] of less than [redacted] The [redacted] for the [redacted] vented PCD (simulated Master Product) was greater than [redacted] refer to Exhibit #M46 Page [redacted]

An observation pertaining to the Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted] was cited due to the selection of the inoculation sites on the device and that there may be other devices more difficult to sterilize. The observation identified the following:

[redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted], Date [redacted] and Final Report [redacted] Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted] refer to Exhibit #M41 and Exhibit #M42, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted] was conducted due to [redacted] The study was conducted to compare a [redacted] and the current PCD (master product).

The purpose was to demonstrate that the packaging change did not make the most difficult to sterilize product more resistant than the currently used PCD. Prior to this comparative resistance study, other [redacted] devices had been evaluated for resistance and compared to the current PCD in other comparative resistance studies. The study describes that various product sites within the [redacted] device, Part No. [redacted]

The study describes [redacted] into the following sites, refer to Exhibit #M42 Page 3:

[redacted]

[redacted]

As the observation cited that there are other models more difficult to sterilize, I compared the [redacted] device used in the comparative resistance study to the [redacted] manufactured by the company, refer to Exhibit #M42 Page [redacted] and Exhibit #M45 Pages [redacted]. The comparison revealed that the [redacted], used in the comparative resistance study, includes an [redacted]

[redacted] refer to Exhibit #M42 Pages [redacted] and Exhibit #M45 Pages [redacted].

In addition, the main purpose of the study was to evaluate the effects of the [redacted] on the product and PCD. The results indicate that the [redacted] devices contained in both the [redacted] demonstrated growth at [redacted] but no growth at [redacted]. The current [redacted] PCDs (Master Product) contained in both [redacted] demonstrated growth at [redacted] through [redacted], refer to Exhibit #M42 Page [redacted]. The study was ended at [redacted] since the PCDs continued to demonstrate growth at [redacted] The final report concludes the following:

[redacted]

Prior to meeting with [redacted], I reviewed the products currently manufactured by the company. [redacted], and Mr. Shirley, provided an overview of the products and answered questions pertaining to the manufacture, design and assembly of the products. On 02/12/04, I met with [redacted], to discuss the comparative resistance study [redacted] demonstrated and discussed the rationale for the inoculation points selected for the [redacted] devices included in Comparative Resistance Study Laboratory No. [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites. This issue is resolved as the study demonstrates the PCD is [redacted] than the device.

Also, [redacted] explained that the [redacted] were not calculated for some of the comparative resistance studies as it is a reference point that is theoretical as the studies are conducted in [redacted] vessels to get direct comparisons between the devices and PCD's. He stated the [redacted] provide a general reference point, but the information of value is the data, or time in minutes, that demonstrate

either growth or no growth. He stated the device in question should be less resistant to sterilization than the PCD, which is demonstrated by the results of the data. [redacted] brought the data and results of all the comparative resistance studies and offered to calculate the [redacted] of any that were not calculated. On this particular day, I did not request [redacted] calculate the [redacted], but did request them for a later date.

On 02/26/04, Mr. Shirley provided a document from [redacted], dated [redacted], which included the [redacted] for the comparative resistance studies we reviewed that were lacking the calculation, refer to Exhibit #M46. The [redacted] for Comparative Resistance Study Laboratory Report No. [redacted], demonstrate the that the most resistant areas of the [redacted] devices in both [redacted] had a [redacted] of less than [redacted] The [redacted] for the [redacted] PCD (simulated Master Product) was greater than [redacted], refer to Exhibit #M46 Pages [redacted]

An observation pertaining to the Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted] was cited due to the selection of the inoculation sites on the device. The observation identified the following:

[redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted], Date [redacted], and Final Report Comparative Resistance Study Laboratory No. [redacted], Report Date [redacted], refer to Exhibit #M43 and Exhibit #M44, respectively. Based on the review of the sterilization validation reports and other comparative resistance studies, this Comparative Resistance Study Laboratory No. [redacted], was conducted due to [redacted]. The study was conducted to compare the new qualification of [redacted] for the [redacted] devices to the current PCD.

The study describes inoculating the [redacted]s device by [redacted]. As described in the observation, the report describes the inoculation site of the product as follows:

[redacted]

[redacted]

Prior to meeting with [redacted], I reviewed the products currently manufactured by the company. [redacted], and Mr. Shirley, provided an overview of the products and answered questions pertaining to the manufacture, design and assembly of the products. I reviewed the type of devices manufactured by the company and compared the products. A comparison of the devices indicates that the [redacted] Previous comparative resistance studies demonstrate that the PCD device is more [redacted], refer to Exhibit #M42.

On 02/12/04, I met with [redacted], to discuss the comparative resistance study. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the [redacted] device included in Comparative Resistance Study Laboratory No. [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites. This issue is resolved as the study demonstrates the PCD is more difficult to sterilize than the device.

Also, [redacted] explained that the [redacted] were not calculated for some of the comparative resistance studies as it is a reference point that is theoretical as the studies are conducted in [redacted] vessels to get direct comparisons between the devices and PCD's. He stated the [redacted] provide a general reference point, but the information of [redacted] that demonstrate either growth or no growth. He stated the device in question should be less resistant to sterilization than the PCD, which is demonstrated by the results of the data. [redacted] brought the data and results of all the comparative resistance studies and offered to calculate the [redacted] of any that were not calculated. On this particular day, I did not request [redacted] calculate the [redacted], but did request them for a later date.

On 02/26/04, Mr. Shirley provided a document from [redacted] dated [redacted], which included the [redacted] for the comparative resistance studies we reviewed that were lacking the calculation, refer to Exhibit #M46. The [redacted] for Comparative Resistance Study Laboratory Report No. [redacted] demonstrates that the most resistant areas of the [redacted] device inside a [redacted] had a [redacted]. The [redacted] for the [redacted] refer to Exhibit #M46 Pages 4.

Prior to reviewing the comparative resistance studies, I reviewed the sterilization validation documents. First, I confirmed that the sterilization chamber currently used by Utah Medical is the same chamber validated in the initial validation conducted in early and late [redacted] and completed in [redacted], respectively. [redacted], Consultant, provided a Facility Master Record document from [redacted], refer to Exhibit #M47. The Facility Master Record confirms that the sterilization facility is the same, but has changed ownership, refer to Exhibit #M47. The sterilization facility has been in operation since [redacted] The

facility was owned by [redacted] in [redacted] and then was purchased by [redacted] in [redacted] acquired the sterilization facility in [redacted] Since the [redacted] validation, Utah Medical continues to use the [redacted], at the sterilization facility.

Next, I reviewed the [redacted] Sterilization Validation Protocol No. [redacted], Issue Date [redacted], and [redacted] Validation Test Protocol and Summary Results, Document No. [redacted] Date [redacted] refer to Exhibit #M48 Pages [redacted] and Exhibit #48 Pages [redacted]. The validation approval for the summary report is dated [redacted] This validation was conducted, with product and the Process Challenge Device (PCD/Master Product), soon after the comparative resistance study for the PCD was completed, refer to Exhibit #M48 Pages 32-46.

A subsequent validation was performed later in [redacted] and completed in early [redacted] I, Investigator Wilkins, reviewed the [redacted] Sterilization Validation Protocol No. [redacted], Issue Date [redacted], and [redacted] Cycle Validation Test Protocol, Document No. [redacted], Date [redacted], refer to Exhibit #M48 Pages [redacted] and Exhibit #M49 Pages [redacted] respectively. The company followed the [redacted] Sterilization Validation Protocol, Protocol No. [redacted], and [redacted] Cycle Validation Protocol, Document No. [redacted], to execute the [redacted] sterilization validation, refer to Exhibit #48 Pages [redacted] and Exhibit #M49 Pages [redacted] respectively. The completed and summarized [redacted] Cycle Validation Test Protocol, Document No. [redacted] was approved on [redacted] and includes the following information, refer to Exhibit #M49 Pages [redacted].

[redacted]

The validation was conducted between [redacted] to [redacted] and was based on ANSI/AAMI/ISO 11135:1994 microbiological indicator overkill method. I reviewed the sterilization validation binders containing the data and results of the validation. The validation was conducted with the [redacted] preconditioning [redacted] and [redacted] sterilization chamber [redacted] with both product and PCD's were run and the sterility test results were [redacted] for growth, refer to Exhibit #M50 Pages [redacted]. A few of the documents from the [redacted] Validation [redacted] and [redacted] Validation [redacted] validation binders were obtained as copies and included the following:

- A few pages from the Design Qualification, Preconditioning [redacted], refer to Exhibit #M50 Pages [redacted]
- Final Report [redacted] Protocol [redacted] for the Validation of the New Pre-Conditioning [redacted] located at [redacted], refer to Exhibit #M50 Pages [redacted]
- Data graphs for Empty Chamber Runs for [redacted] sterilization chamber [redacted], refer to Exhibit #M50 Pages [redacted]

- Memorandum for Sterilization Validation File [redacted] Subject: Empty Chamber Temperature Profile, Date [redacted] documents that [redacted] locations were established using an empty chamber, Protocol [redacted] refer to Exhibit #M50 Page [redacted]
- [redacted] Quantity of [redacted] required, Date [redacted], refer to Exhibit #M50 Page [redacted]
- [redacted] Location Maps, refer to Exhibit #M50 Pages [redacted]
- Drawing and description for Master Product for Sterilization, Catalog No. [redacted] Date [redacted], refer to Exhibit #M50 Pages [redacted]
- [redacted] Cycle Parameters (Listing) for [redacted] refer to Exhibit #M50 Pages [redacted]
- [redacted] Cycle Parameters (Listing) for [redacted] refer to Exhibit #M50 Pages
- Listing of products, [redacted] included in the validation [redacted] cycle runs, refer to Exhibit #M50 Pages [redacted]
- Several pages from the [redacted] sterility test results for the validation, refer to Exhibit #M50 Pages [redacted]

All the data was verified including cycle parameters for the [redacted] cycle runs. The results of the sterility and LAL tests were reviewed and verified.

The [redacted] sterilization process was assessed and an [redacted] revalidation was performed in [redacted] following the [redacted] Test Protocol, Document No. [redacted] Revision [redacted] Date [redacted], refer to Exhibit #M51. The data and results were reviewed.

Due to a [redacted], a product density study was conducted following Product Density Test Protocol, Document No. [redacted], Revision [redacted] Revision Date [redacted], refer to Exhibit #M52. The results are summarized in the Product Density Test Report, Document No. [redacted], Revision [redacted] Date [redacted] refer to Exhibit #M53. The data and summary report indicate that the [redacted] did not change the product density as the density of the [redacted] product was equivalent to the density of the [redacted] product, refer to Exhibit #M53 Page

After the Product Density results were finalized, the company conducted an [redacted] sterilization cycle assessment and revalidation by following [redacted] Document No [redacted], Revision [redacted] Revision Date [redacted], refer to Exhibit #M54. The data and results were reviewed. The [redacted] Document No. [redacted] Revision [redacted] Date [redacted] outlines the data contained in the packet, refer to Exhibit #M55.

In [redacted] the company conducted an [redacted] sterilization re-validation to increase the [redacted] by following the [redacted] Cycle Validation for [redacted], Document No. [redacted], Revision [redacted] Revision Date [redacted], refer to Exhibit #M56. The [redacted] Cycle Validation for [redacted] Test Report, Document No. [redacted], Revision [redacted], Date [redacted], outlines the validation data

contained in the binders, refer to Exhibit #M57 Pages [redacted] I reviewed the protocol, test report summary, and data contained in the validation binders and copies of some of the records were obtained, refer to Exhibit #M57. The validation runs document that in addition to including product and PCD's in the [redacted] runs, the density was also augmented by the addition of product to each carton to make the cartons more dense than any product [redacted] sterilized, refer to Exhibit #M57 Page[redacted]. The information and memo documents that the most dense product sterilized is Catalog Number [redacted] which has a density of [redacted] and the load density of the containers for this validation was augmented to [redacted] by the addition of product to each carton, refer to Exhibit #M57 Page The data demonstrates the process was validated.

In addition, I reviewed the sterilization revalidation conducted by following [redacted] Cycle Revalidation Test Protocol, Document No. [redacted], Revision Date [redacted], refer to Exhibit #M58. The revalidation protocol was executed to demonstrate that no inadvertent process changes occurred that could significantly affect the previously validated cycle. An outline of the data contained in the validation binders is included in [redacted] Cycle Revalidation Test Report, Document [redacted], Revision [redacted] Date [redacted] refer to Exhibit #M59 Pages [redacted] Copies of some of the data and records included in the validation binders were obtained, refer to Exhibit #M59.

In [redacted], the company conducted a [redacted] sterilization revalidation assessment for [redacted] The revalidation assessment conducted by [redacted] titled [redacted] and the associated data was reviewed. Copies of some of the data and revalidation assessment report were obtained, refer to Exhibit #M60.

The company conducted a [redacted] revalidation assessment by following the [redacted] Sterilization Revalidation Assessment Test Protocol, Document No. [redacted], Revision [redacted] Revision Date [redacted] refer to Exhibit #M61. The [redacted] Sterilization Revalidation Assessment [redacted], Test Report, Document No. [redacted], provides a summary of the assessment, refer to Exhibit #M62 Pages Copies of a few of the revalidation assessment records were obtained, refer to Exhibit #M62.

In addition, I reviewed the Revalidation Assessment [redacted], Test Report, Document No. [redacted], Revision [redacted] Date [redacted], refer to Exhibit #M63. The revalidation assessment was conducted by following the [redacted] Sterilization Revalidation Assessment Test Protocol, Document No. [redacted], Revision [redacted] Revision Date [redacted] refer to Exhibit #M61 and Exhibit #M63 Pages [redacted] Copies of a few of the revalidation assessment records were obtained, refer to Exhibit #M63.

In summary, Utah Medical has conducted sterilization validations, revalidations and [redacted] validation assessments. The [redacted] sterilization validations were conducted in accordance with ANSI/AAMI/ISO 11135:1994 microbiological indicator overkill method. The sterilization validation [redacted] runs were performed by increasing the density of the loads to a [redacted]

and using product and process challenge devices. The company has conducted comparative resistance studies on products to demonstrate that the PCD's are more resistant to sterilization than the products.

2. **There is no documentation that a comparative resistance study was performed to demonstrate that the [redacted] is less resistant to the [redacted] sterilization than the [redacted] product, in order to justify utilization of the same sterilization process.**

CORRECTION

Written by Investigator Wilkins.

On the dates including 02/10-12/04, 02/17/04, and 02/23-25/04, I, Investigator Wilkins, reviewed records related to the sterilization process in order to assess the issues related to this observation. I reviewed all the records related to the sterilization validations, annual sterilization assessments, comparative resistance studies, environmental monitoring, and DHR sterilization cycle records, refer to the Production & Process Controls Subsystem subsection under the Manufacturing/Design section.

The company has conducted approximately [redacted] Comparative Resistance studies for the purpose of demonstrating that the process challenge device (PCD or Master Product) is [redacted] than the devices manufactured by the company, refer to Exhibit #M32.

I requested and obtained, from [redacted], the Comparative Resistance Study Protocol No. [redacted], Issue Date [redacted], for the [redacted]

This observation was cited due to the lack of a Comparative Resistance Study for the [redacted] The company initiated a comparative resistance study on [redacted]

I reviewed the Comparative Resistance Study, Protocol No. [redacted], Date [redacted] and Final Report Comparative Resistance Study Laboratory No. [redacted] Report Date [redacted] refer to Exhibit #M64 and Exhibit #M65, respectively. The study was conducted to evaluate whether the [redacted] is less resistant to EO than the current PCD, refer to Exhibit #M65.

The study describes inoculating the [redacted], refer to Exhibit #M65 Page

The final report describes the inoculation site of the product as follows:

The [redacted] which is the current PCD used in routine processing and all sterilization validations completed since [redacted] was inoculated with [redacted] refer to Exhibit #M65 Page [redacted] The results indicate the [redacted], refer to Exhibit #M65 Pages [redacted] All the PCDs demonstrated growth at [redacted], refer to Exhibit #M65 Pages [redacted] At an exposure time of [redacted], the test product demonstrated [redacted] nd all PCD's demonstrated [redacted] refer to Exhibit #M65 Pages [redacted]

Prior to meeting with [redacted] I reviewed the products currently manufactured by the company. [redacted], and Mr. Shirley, provided an overview of the products and answered questions pertaining to the manufacture, design and assembly of the products.

On 02/12/04, I met with [redacted] to discuss the comparative resistance study. [redacted] demonstrated and discussed the rationale for the inoculation points selected for the [redacted] device included in Comparative Resistance Study Laboratory No. [redacted] was able to demonstrate and provide the rationale for the selected inoculation sites.

Also, [redacted] explained that the [redacted] were not calculated for some of the comparative resistance studies as it is a reference point that is theoretical as the studies are conducted in [redacted] vessels to get direct comparisons between the devices and PCD's. He stated the [redacted] provide a general reference point, but the information of value [redacted] He stated the device in question should be less resistant to sterilization than the PCD, which is demonstrated by the results of the data. [redacted] brought the data and results of all the comparative resistance studies and offered to calculate the [redacted] of any that were not calculated. On this particular day, I did not request [redacted] calculate the [redacted] but did request them for a later date.

On 02/26/04, Mr. Shirley provided a document from [redacted], which

included the [redacted] for the comparative resistance studies we reviewed that were lacking the calculation, refer to Exhibit #M46. The [redacted] for Comparative Resistance Study Laboratory Report No. [redacted] ' demonstrates that the

[redacted]

B. Regarding LAL Testing:

[redacted], Rev [redacted] Sterilization Load Preparation, Section [redacted], required LAL samples to be identified for submission to the testing laboratory after sterilization. The current version of this procedure Revision [redacted], Section [redacted] directs for LAL samples to be pulled and sent to the lab before sterilization. The change occurred under change proposal [redacted] and was approved on or about [redacted] The reason stated for the change was [redacted] LAL testing detects endotoxins that are released from the cell wall of dead bacteria. The test should not be performed until the device has completed all steps of processing to assure the correct levels are measured. Therefore, the current testing is inadequate because it is not performed after the sterilization.

CORRECTION

Written by Investigator Wilkins.

The company initiated Change Proposal (CP) No. [redacted] to modify Section [redacted] of the [redacted] Sterilization Load Preparation procedure, Document No. [redacted] Revisior [redacted] Revision Date [redacted] by removing the following:

[redacted]

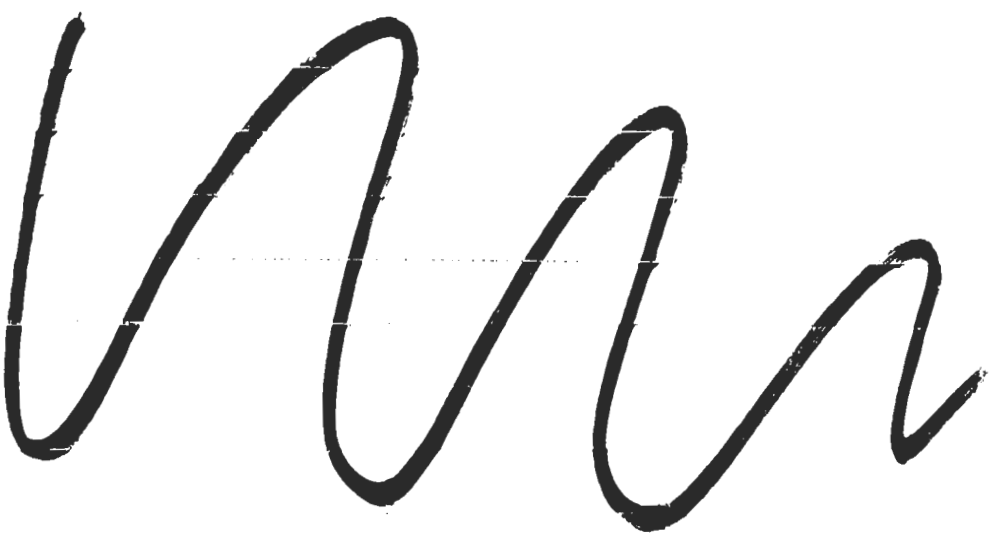
The Description of Change section of CP No. [redacted] describes the following:

[redacted]

Section [redacted] of the current procedure, [redacted] Sterilization Load Preparation, Document No. [redacted]; Revision [redacted] Revision Date ([redacted] provides the following instructions:

The company is now processing the LAL test sample through the sterilization process and then submitting the test sample to the testing laboratory.

In order to verify that the procedure was implemented and followed, I sampled device history records for review. On 02/23/04 and 02/24/04, I reviewed the following sterilization process/retort cycle records that required the submission of product for LAL testing:



The review of the sterilization cycle records confirmed that the product samples submitted for LAL testing were sent to the testing laboratory after the sterilization process was completed.

As an example, sterilization cycle record Process/Retort [redacted] documents that Pallet No. [redacted] included the box containing the product samples to be submitted for LAL testing, refer to Exhibit #M68 Page [redacted] The documentation recorded on the Submission Form includes the [redacted] and other relevant information, refer to Exhibit #M68 Pages [redacted] The Process/Retort No. [redacted] sterilization cycle record includes the following documents:

- Submission Forms, refer to Exhibit #M68 Pages [redacted]
- Sterilization cycle processing records, refer to Exhibit #M68 Pages [redacted]

- Final Report Biological Indictor Sterility Test, Laboratory No. [redacted] refer to Exhibit #M68 Pages [redacted]
- Final Report Limulus Amebocyte Lysate (LAL) Test, [redacted] Laboratory No. [redacted] refer to Exhibit #M68 Pages [redacted]
- Final Report Limulus Amebocyte Lysate (LAL) Test, [redacted] Laboratory No. [redacted], refer to Exhibit #M68 Pages [redacted]
- Final Report Limulus Amebocyte Lysate (LAL) Test, [redacted] Laboratory No. [redacted], refer to Exhibit #M68 Pages [redacted]
- Final Report Limulus Amebocyte Lysate (LAL) Test, [redacted] Laboratory No. [redacted], refer to Exhibit #M68 Pages [redacted]
- Final Report Limulus Amebocyte Lysate (LAL) Test, [redacted] Laboratory No. [redacted], refer to Exhibit #M68 Pages [redacted]

The company is processing the LAL test after the sterilization process is completed.

C. Regarding Real Time Packaging studies:

1. **Test Protocol, [redacted], Rev. [redacted], Real Time Packaging and Integrity Test, is inadequate in that it does not include the following:**
   a. **a plan for storage of samples, including, storage and environmental conditions to be controlled and monitored and data to be collected;**
   b. **simulation of shipping & handling stresses plan including vibration test, temperature extreme challenges, actual shipping and intentional mishandling; and,**
   c. **organizational units that are responsible for the various phases of shelf-life testing.**

Correction

Written by Investigator Wilkins.

This observation is resolved. The observation cited during the 2003 inspection of the company indicates that the Real Time Packaging Integrity Test Protocol, Document No. [redacted] Revision [redacted] Revision Date [redacted] lacked the following, refer to Exhibit #M70:

- Storage Environmental Conditions
- Shipping & Handling Stresses Plan

- Organizational Responsibilities for the conduct of Shelf-Life Testing

The company provided a memorandum concerning observation 1C of the previous inspection dated 02/13/04, refer to Exhibit #M69. The memorandum includes a sentence that [redacted], refer to Exhibit #M69. When asked, Mr. Ben Shirley stated the company does not believe there is a requirement for conducting real-time aging packaging studies. I, Investigator Wilkins, stated that real-time aging of product and packaging may not be necessary if accelerated aging studies were conducted and documented with a rationale for not conducting real-time aging studies. Also, I stated that in some instances, product Premarket Approvals (PMA's) or 510(K)'s may, depending on the product, require real time packaging studies as part of the packaging validation to confirm the package integrity and materials for the actual shelf-life of the product.

The company's response memorandum also indicates Utah Medical revised the Real-Time Aging protocol on [redacted] refer to Exhibit #M69. The revised Real Time Packaging Integrity Test Protocol, Document No. [redacted] Revision [redacted], Revision Date ([redacted], added the following criteria:

- Sample Selection and Environmental Conditions, refer to Exhibit #M71 Page 3
- Sample Preparation, refer to Exhibit #M71 Page [redacted]
- Documentation, refer to Exhibit #M71 Page [redacted]

In addition, I, Investigator Wilkins, verified the assignment of responsibilities for the development of protocols and conduct of the tests and/or validations. In the firm's response memorandum, they indicate that the responsibilities are defined in the Human Resources Administration procedure, Document No. [redacted] Revision [redacted] Revision Date [redacted], refer to Exhibit #M69. I reviewed the Human Resources Administration procedure, which defines the job responsibilities of the various positions within the organization. This procedure provides an overview of the job descriptions, but the firm has other procedures that better define and assign responsibility for the writing of test protocols and the execution of tests.

In my review of other procedures, I determined that the responsibilities for the development of test protocols and the execution of testing are defined in the following procedures:

- Quality Manual, Revision [redacted] Section [redacted] assigns the responsibility for product design process to a [redacted], refer to Exhibit #M72 Page [redacted]
- Quality Manual, Revision [redacted] Section [redacted] under the [redacted] subsection assigns the responsibility to the [redacted] which includes [redacted], refer to Exhibit

#M72 Page

- Manufacturing Process Qualification and Validation procedure, Document No. Revision , Revision Date , assigns the responsibilities of ensuring the qualification and validation procedures are written, performed, and documented to the personnel, refer to Exhibit #M73 Page
- Manufacturing Process Qualification and Validation procedure, Document No. Revision Revision Date assigns the responsibilities of verifying that the required qualifications and validations procedures are completed and reviewed to the refer to Exhibit #M73 Page

The firm has additional procedures that assign responsibility, which include the Directive and Development of Products, Document No. , Revision Revision Date Experimental Products Document Control System, Document No. , Revision Revision Date , and, Sterile Packaging Design, Document No. , Revision Revision Date , (Exhibit #M74 Page

I inquired if the company followed any standards for packaging validation. Mr. Shirley stated he would check with to verify if a packaging standard is referenced or followed by the company. During my review of documents, I determined the company follows the requirements of ISO 11607 – Packaging for Terminally Sterilized Medical Devices, 1st Edition, 1997-02-15. The standard indicates that the real time packaging studies are recommended, but not necessary if accelerated packaging studies were performed and documented.

A review of the firm's 510(k)'s indicated that there was no requirement to conduct real time packaging studies. The firm follows the ISO 11607 standard for terminally sterilized medical devices and conducted accelerated aging studies to verify the shelf-life of the packaging materials and products. The company performs accelerated aging studies supplemented by real time packaging studies to verify the shelf life expiration date.

On 02/23/04 and 03/01/04, Mr. Ben Shirley stated that repeat tests conducted under the revised Real Time Packaging Integrity Test Protocol, Revision have been initiated for the pouches and trays and will be completed in or the pouches and trays, respectively.

2. Test Report, Rev. , Real Time Packaging Integrity Test, for devices in pouches and trays, and completed in accordance with does not define the following:

a. the lots of products that were placed on real time studies;

b. what environmental and storage conditions the study packaging was subjected

to; and,

c. shipping and handling tests performed on the devices.

CORRECTION

Written by Investigator Wilkins.

This observation is resolved. The observation cited during the 2003 inspection of the company indicates that the Real Time Packaging Integrity Test Report, Document No. [redacted] Revision [redacted] Revision Date [redacted], lacked the following, refer to Exhibit #M70:

- Lot Numbers of Product
- Environmental and Storage Conditions
- Shipping & Handling Stresses Plan

The company provided a memorandum concerning observation 1C of the previous inspection dated 02/13/04, refer to Exhibit #M69. The memorandum includes a sentence that '[redacted] to Exhibit #M69. When asked, Mr. Ben Shirley stated the company does not believe there is a requirement for conducting real-time aging packaging studies. I, Investigator Wilkins, stated that real-time aging of product and packaging may not be necessary if accelerated aging studies were conducted and documented with a rationale for not conducting real-time aging studies. Also, I stated that in some instances, product Premarket Approvals (PMA's) or 510(K)'s may, depending on the product, require real time packaging studies as part of the packaging validation to confirm the package integrity and materials for the actual shelf-life of the product.

The memorandum, dated [redacted], indicates that UTMD believes adequate tests were previously completed, but that repeat tests under the revised protocol, Document No. [redacted], Revision [redacted] have been initiated, refer to Exhibit #M69. On 02/23/04 and 03/01/04, Mr. Ben Shirley stated that repeat tests conducted under the revised Real Time Packaging Integrity Test Protocol, Revision [redacted] have been initiated for the [redacted] pouches and [redacted] trays and will be completed in [redacted], for the pouches and trays, respectively.

I, Investigator Wilkins, inquired if the company followed any standards for packaging validation. Mr. Shirley stated he would check with [redacted], to verify if a packaging standard is referenced or followed by the company. During my review of documents, I determined the company follows the requirements of ISO 11607 – Packaging for Terminally Sterilized Medical Devices, 1st Edition, 1997-02-15. The standard indicates that the real time packaging studies are

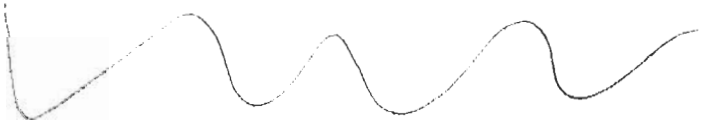
recommended, but not necessary if accelerated packaging studies were performed and documented.

A review of the firm's 510(k)'s indicated that there was no requirement to conduct real time packaging studies. The firm follows the ISO 11607 standard for terminally sterilized medical devices and conducted accelerated aging studies to verify the shelf-life of the packaging materials and products. Even though their procedures do not require the performance of real time packaging studies, the company performs accelerated aging studies supplemented by real time packaging studies to verify the shelf life expiration date.

I reviewed the Accelerated Aging and Package Integrity Test, Protocol No. , and Final Report for Accelerated Aging and Package Integrity Test, Laboratory No. to verify the accelerated aging tests conducted on packaging materials to evaluate the barrier properties of the packaging materials following a accelerated aging period. The results indicate that the packaging materials demonstrate a sterile barrier properties following an extreme bacterial aerosol challenge after exposure to a accelerated aging.

In addition, to verify functionality testing of a product after accelerated aging tests, I requested any information related to the Real Time Packaging Integrity Test Report, , Revision , Revision Date , refer to Exhibit #M75. A review of Test Report No. revealed that the Appendix section referenced Change Proposal (CP) refer to Exhibit #M75 Pages A review of included the testing raw data from Test Report . A few sections of , were obtained, refer to Exhibit #M76.

Test Report referenced the Pouch or Tray Seal Testing procedure, refer to Exhibit #M75 Page I reviewed the Pouch or Tray Seal Testing procedure, Document No. , which outlines the pressure testing of packaging seals, refer to Exhibit #M77. In addition, the following procedures referenced or followed during the execution of the Real Time Packaging Integrity Test were reviewed:



I requested the device history record (DHR) for the products manufactured for the testing described in the Real Time Packaging Integrity Test Protocol and Report. Mr. Shirley provided A review of the information documented in verified the documentation was relevant to the test protocol and test report.

In addition, [redacted] indicates the test articles were exposed to [redacted] and stored at ambient temperature and humidity for [redacted], refer to Exhibit #M75 Page [redacted] A review of the Process/Retort Cycle records No. [redacted] and [redacted], referenced in [redacted], revealed the test articles were exposed to [redacted]

Since the company relies on accelerated aging tests to verify the shelf-life of the product, I decided to verify the accelerated aging test data for the [redacted]. The [redacted] Redesign Qualification, Document No [redacted] Revision [redacted] Date [redacted] includes the accelerated aging tests for the product among other elements included in the testing, refer to Exhibit #M78. Section [redacted] titled Shelf Life Processing, of the [redacted] Qualification Test Protocol, Document No. [redacted] requires the following processing steps for the accelerated aging, refer to Exhibit #M78 Page [redacted]

[redacted]

The Environmental and Accelerated Aging Tests procedure, Document No. [redacted], Revision [redacted] Revision Date [redacted] describes and defines the environmental test parameters and accelerated aging requirements, refer to Exhibit #M79.

The [redacted] Qualification Test Report, Document No. [redacted] Revision [redacted], Revision Date [redacted] documents the results to qualify the dimensional modifications made to the device, [redacted], refer to Exhibit #M80. Change Proposal (CP) [redacted] was initiated to allow for [redacted]

The Test Report No. [redacted], Revision [redacted] documents the following:

[redacted]

I reviewed the raw data beginning with the Extra Process Work Order (EPWO) [redacted] for the [redacted] product manufactured between [redacted], refer to Exhibit #M81. The [redacted] includes a notation that the product be returned to the [redacted]

, refer to Exhibit #M81 Page

Next, I verified that the product was I reviewed the following sterilization process cycle records:

The process/retort sterilization cycle records did not specifically reference the , but engineering box containing the products of was labeled and identified with the engineer in charge of the product and dates. The engineer name and dates, identified with the engineer box documented within the sterilization cycle records, provided the linkage to the product manufactured under

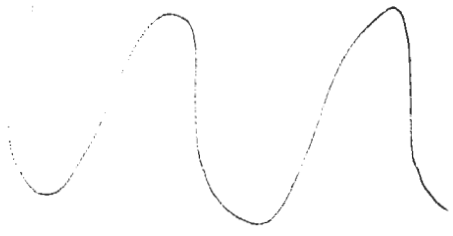
Next, I reviewed the data related to the of environmental aging performed per procedure The Environmental Chamber Log revealed that the product samples for were placed in the environmental chamber for between the dates of The product was placed in the environmental chamber for under the conditions described under the Environmental and Accelerated Aging Tests procedure, Document No. refer to Exhibit #M79 Page

After reviewing the data for the environmental aging test, I reviewed the data for the accelerated aging tests. The product samples were placed in to simulate a shelf-life. The Log documents that the product samples were placed in the

Once the review of the raw data associated with the shelf life processing tests was completed, I reviewed the product inspection and test data as outlined in Section , Inspection and Testing section, Qualification Test Protocol, Document No. , refer to Exhibit #M78 Page

The leak test was performed according to (Leak Tests) Pressure Tubing Drip Set and procedure, Document No. , Revision , Revision Date The visual inspection and leak test data is included in Test Report No. , under the section titled "Final Qualification Test Results refer to Exhibit #M80 Pages The pull test results in Test Report No. under the section titled "Final Qualification Pull Test Results

documented that samples from each group were pulled at the , refer to Exhibit #M80 Pages The pull test results were as follows:



The Conclusion section, Section , of the Qualification, Document No. concludes that the base plate is released for production and distribution as qualified for ; and a shelf life.

In addition, the raw data for the test results documented in Test Report No. was reviewed to ensure the data reflected the same information as summarized in the final report. The data was verified. In order to verify the results of the pull test, I reviewed the Design Specification, Document No. , Revision -Revision Date , refer to Exhibit #M82. The bonded connection strength specification listed under Section is defined as the bond connection strength must not break or crack at less than of force. The pull strength test results in Test Report No. demonstrate that the bond connection strength is greater than ; refer to Exhibit #M80 Pages

The company has conducted accelerated aging tests for packaging and is conducting real time packaging tests.

D. Regarding Molding:

1. **There is no approved extrusion process validation demonstrating the firm's use of the setup parameters to operate the extrusion molding equipment. The set-up parameters are copied from the previous extrusion molding set-up sheet, as confirmed by firm personnel.**

   Written by Investigator Medina. This item was observed to not have been corrected. See current FDA-483 item numbers 1a and the "Objectionable Conditions" section of this report.

2. **There is no process validation for molding the female luer to show approved setup and operating parameters**

Written by Investigator Medina. This item was observed to not have been corrected. See current FDA-483 item numbers 1b, 1c, and 1d and the "Objectionable Conditions" section of this report.

The injection molding operations associated with the female luer were again reviewed during this inspection to determine if any additional validation activities were conducted upon this part which was noted on the FDA-483 during the 2003 inspection. Mr. Shirley stated that the firm has not conducted additional validation or qualification activities associated with injection molding operations as they currently exist at the firm, and have existed since the previous inspection. Additionally, Mr. Shirley stated that drawings and associated injection molding processing procedures have not been changed since the previous inspection. These documents were again collected during this inspection and are evidenced as follows:

EXHIBIT	INJECTION MOLDING ASSOCIATED DOCUMENTS
L91	Drawing entitled dated
L92	MOLDING SET-UP SHEET ; Document Number Revision for Part Number
L93	BOO (Bill of Operation); Process number dated (the date of printing). Mr. Shirley stated that this has not changed since the previous inspection.
L94	QUALITY ASSURANCE PROCEDURE number entitled "MOLDING AND EXTRUSION INSPECTION PROCEDURE"; Revision dated
L95	QUALITY ASSURANCE PROCEDURE number entitled ; Revision dated

E. Regarding Qualifying the Intran Plus for

Procedures for validation of the for IUP devices, as described in Test Protocol, , Rev. and Test Report, , Qualifying Intran Plus for a are inadequate to allow for as described in D because the TP and TR fail to include or evaluate:

1. **test reports for sterilization exposures;**

2. **identification of the lots of finished product subjected to testing; and,**

3. **an analysis of residuals after the**

CORRECTION

Written by Investigator Wilkins.

In response to this observation, the company revised the Qualification of Intran Plus For A Test Report, Document No. , Revision , Revision Date under Change Proposal (CP) and CP

The Qualification of ; For Test Report, Document No. Revision , Revision Date was modified to , refer to Exhibit #M83 Page

Due to typographical errors to the Qualification of For A Test Report, Document No. , Revision , Revision Date , was revised to correct the refer to Exhibit #M84 Page

The observation cited during the 2003 inspection was due to the lack of cycle retort numbers and lot numbers. The firm had the sterilization cycle records and DHR lot history records but the numbers were not recorded on the final test report. I requested and reviewed the following records and associated data:

The company corrected 1E1 and 1E2 of this observation by adding the numbers to the test report, but the data existed. In addition, the actual testing and test report were completed on and the subsequent revisions to the test report were only to add the sterilization cycle retort numbers and lot numbers.

The actual test data conducted for leakage current after the and after the had additional failures. The firm does not explain the results. When asked, Mr. Ben Shirley stated that the firm did not consider the failures as an issue because the seams were damp and the

is an extreme worst case scenario. When asked again, Mr. Shirley stated that the manufacturing process for the Intran Plus has been . During the testing reported under Test Report No. the Intran Plus , Revision ' Document No. , Revision Revision Date , to assemble the , refer to Exhibit #M85.

When the company decided to the company performed the Qualification of the and completed a test report. The Qualification of the Test Report, Revision , Revision Date , documents that the product test samples were processed through per procedure , Revision refer to Exhibit #M86 Page The current test, test, and test were performed on the product test samples, refer to Exhibit #M86 Pages

I reviewed and verified the raw data and records associated with Test Report which included the following:

- DHR Extra Process Work Order (EPWO)
- DHR EPWO
- Sterilization Cycle Process/Retort
- Sterilization Cycle Process/Retort
- Sterilization Cycle Process/Retort

The test samples were manufactured under DHR lots, , and each DHR lot was exposed to process cycles.

Next, the product test samples were placed in the environmental chamber for per procedure Revision refer to Exhibit #M79. I verified data for the environmental chamber by reviewing the Environmental Chamber Log.

In addition, I verified the raw data for the current test, test, and test. The raw data is maintained in Change Proposal (CP) refer to Exhibit #M88.

Section of the Test Report No. describes the following:

The raw data for the test is located in , refer to Exhibit #M88 Page The results after the worst case were as follows:

Exhibit M86 Page 5.

The Test Report No. , Revision Revision Date , supersedes the Test Report No. , because that testing was actually conducted on refer to Exhibit #M86 and Exhibit #M84, respectively. The test results documented in Test Report No. did not include failures in the environmental chamber, and unctionality test worst case conditions.

The observations, 1E1 and 1E2, cited during the 2003 inspection are resolved.

The company was also cited for the lack of conducting residuals analysis after exposure to a sterilization during the 2003 inspection. The current DMR for the Device Master Record, Document No. , Revision , Revision Date indicates the are qualified for sterilization process, refer to Exhibit #M89 Page

In order to correct this observation, the company executed the Testing Test Protocol, Document No. Revision Revision Date The current revision of the test protocol, Testing Test Protocol, Document No Revision Revision Date refer to Exhibit #M90. The results are documented in the Test Results Test Report, Document No. , Revisior Revision Date refer to Exhibit #M91.

The device submitted for testing was the because the

contains all the components that may be included in any of the models of the product family members, refer to Exhibit #M91 Page The was submitted to ; records and documented in Sterilization Cycle Process/Retort I requested and reviewed the processing records, Process/Retort Cycle and Process/Retort Cycle to verify the sterilization cycles for the product submitted for testing. After exposing the product test samples to sterilization cycles, the test samples were submitted to the contract laboratory for analysis.

The l analysis test results are documented in the Final Report, , Laboratory No. , Report Issue Date , refer to Exhibit #M92. The results indicate the residual amounts are within acceptable limits.

In addition, the company has also conducted analysis for the devices processed through process cycles. The results are documented in the Test Results Test Report, Document No. , Revision Revision Date , refer to Exhibit #M93. The conclusion section of this test report concludes that the , refer to Exhibit #M93 Page

F. Regarding the gluing process for the IUP device

There is no validation for the gluing process bonding the devices. Functionality testing was performed but the gluing process was not validated.

Written by Investigator Jerndal.

See the firm's response under Section, Observation 1F, Exhibit L10. Attached to that response, is a copy of Test Protocol , Revision , dated IUP Functionality Test." This test protocol purpose is stated as, " The Test Report , Revision , dated Functionality Test", also found in the firm's response, states its purpose as,)." Section on page describes pull testing. Section summarizes the results (listed in pounds) of the pull test of samples of were also tested "For comparison purposes." Section on page describes this pull testing as, That is the catheter according to Mr. Shirley. According to Mr. Shirley, this test report indicated the product, with the design, met the requirement of being at least as good as the design.

The Test Report , Revision dated is also found in the firm's blue book response. Its stated purpose is, " Under "Overview", page of this Test Report, it is stated that,

And further,

Acceptance criteria is stated as,

The raw data supporting this testing was reviewed by Monica Wilkins, during assessment of previous inspection 483 Item #13, which cited design change issues for this same set of test protocol and test reports. See that prior 483 observation 13 discussion for additional discussion.

OBSERVATION 2: Investigators Wilkins (a, c, d) and Medina (b, e, f, g) followed up on this observation.

Software validation activities for computers or automated data processing systems used as part of production and the quality system have not been documented.
Specifically,

The following computer software has not been validated for its intended use:

a) The Document Distribution system

CORRECTION

Written by Investigator Wilkins.

The company has corrected this observation by validating the Document Distribution System. The Document Distribution System is a program that allows for employees to access procedures, in a view only mode, by going through successive indexes. I, Investigator Wilkins, reviewed the Document Distribution System Test Protocol, Document No. Revision Revision Date ; and Document Distribution System Software Definition and system requirements document, Document No. , Revision , Revision

Date refer to Exhibit #94 and Exhibit #M95.

After reviewing the test protocol and system software requirements, I reviewed the Document Distribution System Validation Test Report, Document No. Revision Revision Date (Exhibit #M96), and the associated raw data documented during the actual testing. The results documents that the only variations were caused by the but the content was accurate. In another type of deviation, when the accessed or printed procedure did not include a diagram or drawing, it was because the original file did had not been scanned into the system. Once the drawings were scanned into the system, the issue was corrected, refer to Exhibit #M96.

Written by Investigator Medina.

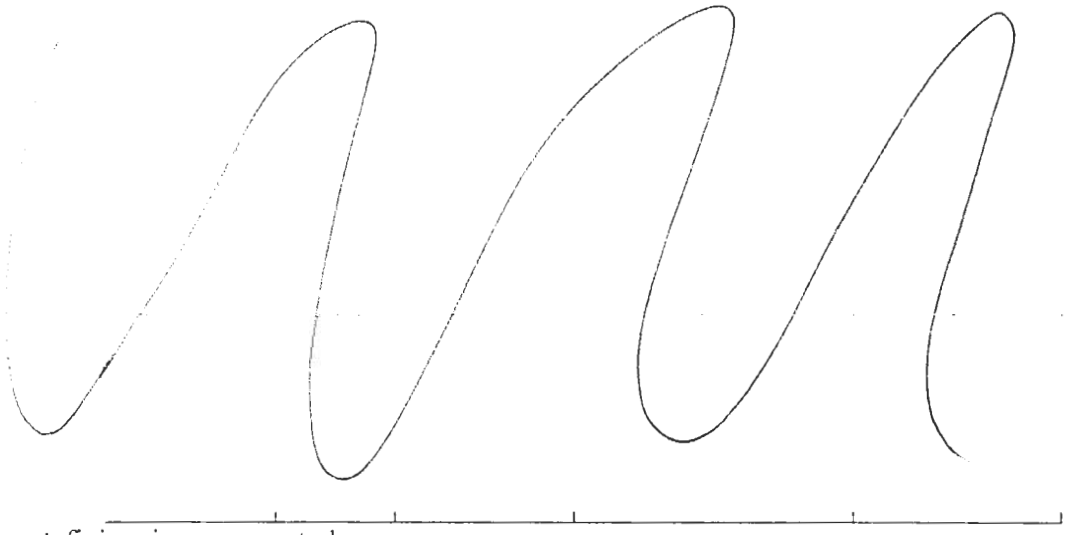
This item was observed to have been partially corrected. See current FDA-483 item number 3c and the "Objectionable Conditions" section of this report. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 2, Page 55 contains information associated with the firm's current Software Validation Plan.

The portion of this observation that was observed to have been corrected is in validation association with the use of for incoming inspection activities. Exhibit L96 is "TEST PROTOCOL" number Revision , dated entitled which describes the test procedure for qualifying nquiry and the subroutine of Direct Results. Exhibit L97 is "TEST REPORT" number , Revision , dated entitled "VALIDATION OF . which states that the raw data is attached to CP The conclusion of this test report states that ." (Exhibit L97, Page

Exhibit L98 is "CHANGE PROPOSAL" number which describes the of the above mentioned software validation. Exhibit L99 is "CHANGE PROPOSAL" number which describes a change to the were identified (Page A summary of the which were changed are as follows:

EXHIBIT	SWITCHING CODE PER	LOT #	LOT	ACTUAL SWITCHING CODE	LOT

	Protocol number and (Exhibit L98)/ Page __		PASS/FAIL	PER (Exhibit L99)/ Page __	PASS/FAIL



No deficiencies were noted.

c) **complaint handling system**

NOT CORRECTED

Written by Investigator Wilkins.

This observation has not been corrected and a similar observation was cited during the current inspection, refer to the discussion under observation 3a of the Objectionable Conditions section of this report. This observation was covered by Investigator Wilkins.

d) **used for maintaining the RGA log**

NOT CORRECTED

Written by Investigator Wilkins.

This observation has not been corrected and a similar observation was cited during the current inspection, refer to the discussion under observation 3b of the Objectionable Conditions section of this report. This observation was covered by Investigator Wilkins.

e) **IUP ; system**
Written by Investigator Medina.

This item was observed to have been corrected. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 2, Page 53 contains information associated with the firm's response to this issue. The response states "...this 'system' does not require software validation because of full verification by visual inspection. Manufacturing personnel 'control and monitor' the of the time during the process to 'ensure that the device conforms to its specifications'...".

Exhibit L113 is "TEST PROTOCOL" number , Revision , dated entitled " which describes the qualification process for evaluating the designed by Exhibit L114 is "TEST REPORT" number , Revision , dated entitled The conclusion of this test report states that ' (Exhibit L114, Page Section) Exhibit L115 is "SOFTWARE SPECIFICATION" number Revision , dated which describes the specifications of the software used for the purpose of operating the

f) **', Rev. program used for components that require ; Device Master Record for) and**
Written by Investigator Medina.

This item was observed to have been partially corrected. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 2, Page 53 contains information associated with the firm's response to this issue. The , and ' " are currently on the firm's Software Validation Plan and has a high priority level which was scheduled to have been completed Mr. Shirley stated that there currently is not a for either of these validation

activities.

Mr. Shirley stated that the tests to ensure that the device has the ability to turn on and off and the is the software that is inherent within the device.

g) **Software used to operate and record test results on the s Final Tester**
Written by Investigator Medina.

This item was observed to have been corrected. Exhibit L116 is "TEST PROTOCOL" entitled "QUALIFICATION OF FINAL TESTER", number , Revision dated which describes the qualification of the final tester for . This qualification addressed the issues as follows:

OBSERVATION 3: Investigators Wilkins and Jerndal followed up on this observation.

The corrective and preventive procedures addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems were not complete.

Specifically,

A. Regarding Finesse ESU complaints:

1. **The Corrective and Preventive Action procedure and the Customer Complaint System procedure are inadequate with regards to the use of failure codes. They do not assure that codes will be uniformly applied as the procedures do not define each code or instruct when each code is to be used. The procedures do not include instructions for changing the codes after evaluation/investigation, nor do they include how this data will be collated and utilized. Review of similar complaints indicated different failure codes were assigned. For example, a review of Finesse complaints in and their failure codes revealed out of complaints coded as failure code " had information describing components as . There were only complaints coded as**

NOT CORRECTED

Note: All the investigators, Investigator Medina, Investigator Jerndal, and Investigator Wilkins, reviewed complaint records to identify correction to this observation.

Written by Investigator Wilkins.

This observation was cited for the lack of defining the failure codes and a similar observation was cited during this inspection. I, Investigator Wilkins, cited this repeat observation under item number 4a1, refer to the discussion under the Objectionable Conditions and Corrective & Preventive Action Subsystem under the Manufacturing/Design section.

2. **Three out of the five Finesse complaints that had stated these were random failures. Complaint letter in indicates this failure typically happens in older systems. This system was of the "'young age' so failure could be contributed to a defective component". The complaint summary for received shows the unit had only been in service since of the complaints showed that units were not old; therefore, they may not be random failures and no corrective or preventive action was opened to evaluate this discrepancy.**

3. **Three out of 18 complaints had no evidence of complaint and service repair history reviews And, six out of 18 complaints had searches of the complaint history and/or service repair history only for the complaint uni The Corrective and Preventive Action procedure is inadequate in that it does not define what type of history search, or to what extent the search should be conducted on complaints. Some complaints examine entire device families while other examine only the affected unit. Further, some complaints included having records reviewed for while others included having records reviewed for .**

B. **Data relating to in-process and finished device testing failures are not analyzed or investigated during IUP catheter manufacturing and, therefore, no corrective or preventive actions have been considered or implemented for any existing or potential causes of non-conforming product or other quality problems.**

Correction

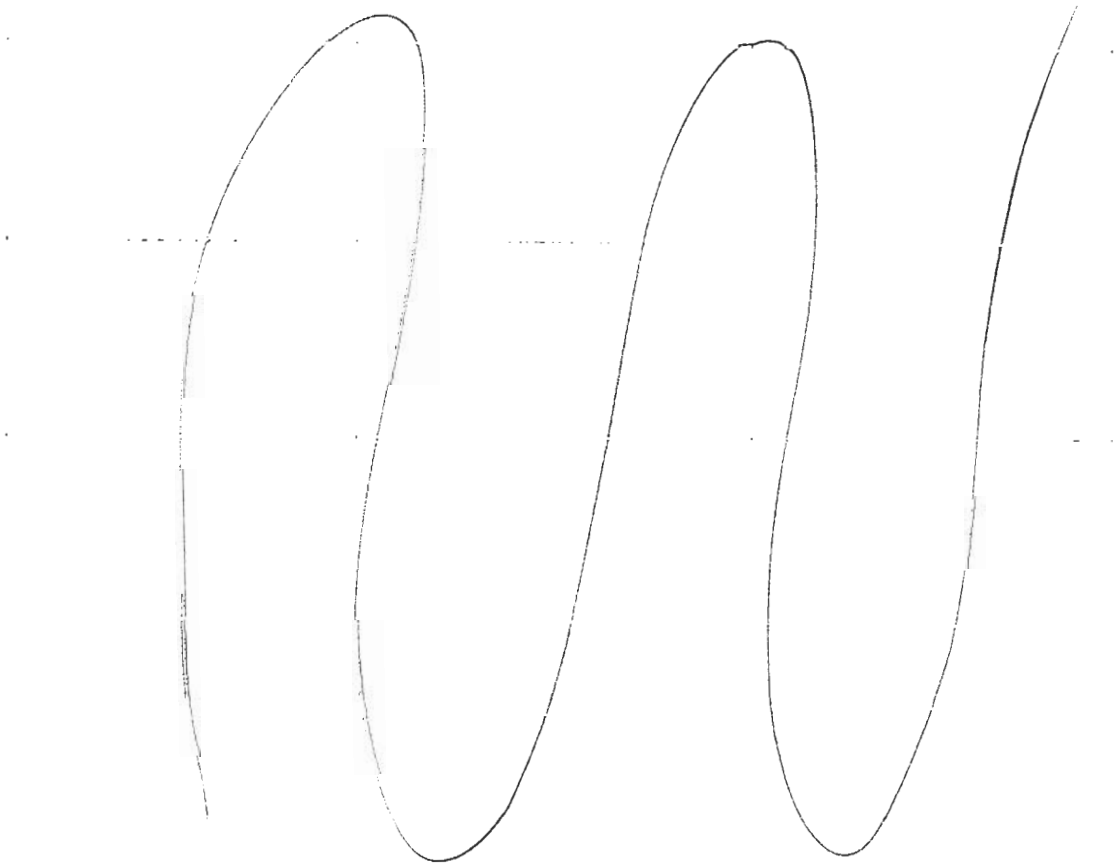
Written by Investigator Wilkins.

During the inspection, Investigator Medina, Investigator Jerndal, and myself (Investigator Wilkins), reviewed Device History Records (DHR's), which included the in-process and finished testing results.

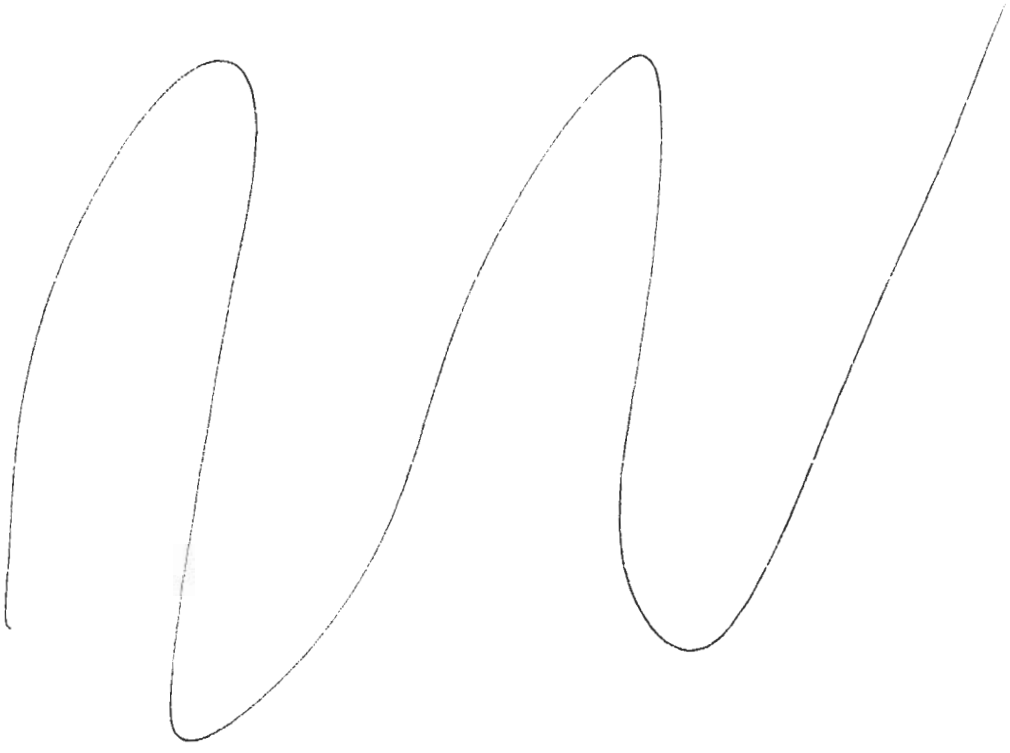
I, Investigator Wilkins, reviewed ✓ DHR's lot histories for numerous devices because they were selected for review in relation to the sterilization cycle records instead of a specific device. The following DHR's were reviewed for devices manufactured between the period of

DEVICE HISTORY RECORDS

LOT NUMBER	PRODUCT NUMBER	PRODUCT NAME



LOT NUMBER	PRODUCT NUMBER	PRODUCT NAME



DHR's that included in-process non-conformances were documented. A review of additional records, such as Nonconforming Material Reports, Corrective Action Reports, and Deviations, Complaints, and Returned Goods Authorizations revealed the company is initiating corrective actions, when necessary, for the records reviewed.

C. **The Corrective and Preventive Action procedure and the Customer Complaint System procedure are inadequate in that they do not include all the instructions needed to close out complaints. When an investigation is transferred from the firm to the vendor, the procedure does not include how to complete the corrective action. For example, complaint was received on a broken, burned and charred . The device was sent to the manufacturer of the , used in this device, for vendor evaluation. The complaint was closed without documentation of receipt or review of the vendor's analysis on the device.**

D. **The Corrective and Preventive Action procedure does not adequately describe when non-conforming incoming product should be evaluated or investigated nor when a corrective and preventive action should be initiated. For example, Non-Conforming Material Reports reviewed for the for the**

failure, [redacted], did not document the evaluation or investigation of the failure and no corrective or preventive action was initiated.

See current FDA-483 observation number 4 and the Objectionable Conditions section of this report.

OBSERVATION 4: Investigators Medina followed up on this observation.

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.
Specifically, [redacted] complaints dated [redacted] were reviewed for cracking/brittle IUP catheters. The original CAPA [redacted] was opened [redacted] and closed [redacted]. There is no documentation of evaluation of patient risk associated with this device failure, and no documentation that an evaluation was made to determine if other devices manufactured by the firm in a similar form or manner may experience a similar failure.

Written by Investigator Medina. During this inspection, I reviewed [redacted] IUP complaints since the previous inspection dated 3/12/03. Patient risk was observed to have been assessed associated with device failure. Additionally, evaluations were conducted to determine if other devices manufactured by the firm experience a similar failure. See current FDA-483 item number 5 and the Objectionable Conditions section of this report associated with CAPA, written by Investigator Jerndal.

This section below was written by Investigator Wilkins.

During this inspection, Investigator Medina reviewed the complaints related to the Intran Plus (IUP) catheter products. The Number of Complaints spreadsheet included in the [redacted] MRB Review report indicates the company received [redacted] IUP product complaints, between [redacted], for brittleness, refer to Exhibit #M5 Page [redacted] After Investigator Medina reviewed the IUP complaints, I, Investigator Wilkins, reviewed the two complaints alleging brittleness received after [redacted], which is the date of the conclusion of the last inspection, for the IUP product line. The complaints are Complaint [redacted] Received Date [redacted] and Complaint # [redacted], Received Date [redacted] The DHR lot history files were reviewed to verify the method of sterilization and the investigation results. The DHR's revealed the products were sterilized by a gamma sterilization process.

For example, Complaint [redacted], Date [redacted], alleged that the catheters are brittle for lot [redacted] The complaint documents that [redacted] IUP catheters were alleged as affected. The

complainant returned 5 IUP catheters. The investigation determined that the l[illegible] was sterilized by a radiation [illegible] sterilization process. I requested and reviewed DHR lot [illegible] and verified that the lot was sterilized by [illegible] sterilization. In [illegible] the company implemented changes in the sterilization method and packaging materials. The company changed from a [illegible] sterilization to [illegible] sterilization method and from [illegible] packaging materials. The lot history revealed the lot of product was manufactured prior to the changes to the sterilization and packaging process.

In addition, the company provided a memorandum, dated [illegible] and risk assessment concerning this observation, refer to Exhibit #M97 Page and Exhibit #M97 Pages [illegible], respectively.

OBSERVATION 5: Investigator Jerndal followed up on this observation.

Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device.

Specifically, between [illegible] and [illegible] complaints accounting for devices were confirmed for adhesion problems at the IUP tip/tubing junction resulting in device failure. There is no evidence that any corrective and preventive action has been documented or implemented for these complaints. Reduction in the number of complaints is not an adequate verification or validation that a corrective and preventive action is effective. Further, these complaints relate to the tip/tubing gluing process, which has not been validated; therefore, there is no assurance that corrective and preventive action has been addressed in retraining.

Written by Investigator Jerndal. See the firm's response to the previous 483, Exhibit L10, Observation 5. That section contains a cover memo describing the rationale why no CAPA was open for this issue. It also contains a copy of Quality Assurance Procedure [illegible] Revision [illegible] dated [illegible] "Customer Complaint System." Also attached is copy of Utah Medical's Risk Assessment Process re: [illegible] form complaints dated [illegible] Also attached is a memo describing results of an IUP Complaint Evaluation with tables showing the number of complaints for the failure mode in question. A copy of this same risk assessment process was collected during the inspection and is attached here as Exhibit R119. The first page is a copy of a Risk Management Plan document dated [illegible] which states that, [illegible]

OBSERVATION 6: Investigator Wilkins followed up on this observation.

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

A. **A MedWatch report was made by a user facility on UTMD complaint ——— for failure of a Finesse Electrosurgical Unit (ESU-110) while in use (lot 112140, serial number ———). The failure occurred during a LEEP procedure in which two cuts had been made and the tissue could not be fully excised without the patient being moved to an adjacent medical facility for surgery to complete the procedure. As of 3/10/03, UTMD had not filed an MDR report for this incident which was reported on 4/15/02 and received by UTMD on ———.**

B. **A MedWatch report was made by a user facility on UTMD complaint ——— for a broken wire on a Letz Loop Electrode (lot 112030) that was in use on a patient during a LEEP procedure. Examination of the device by UTMD found the device to be melted and charred on the depth gauge and that the wire had broken at the depth gauge on both sides. The broken wire was not recovered during the procedure. As of 3/10/03, UTMD had not filed an MDR report for this incident which was reported on 3/21/02 and received, along with the device, by UTMD on ———.**

CORRECTION

Written by Investigator Wilkins.

During the inspection, I, Investigator Wilkins, reviewed 28 complaint records. I verified that the investigations and MDR assessments were complete and documented for all the complaints reviewed.

In addition, I reviewed the five files that were reported as Medical Device Reports and two files in which the company received a MedWatch report but were not reported as MDR's, refer to Exhibit #M98 Page 1 and Exhibit #M98 Page 2, respectively.

The MDR records were reviewed in detail with Mr. Cornwell and he provided user instructions, labeling, and brochures related to the use of the product. He explained the company's investigation results for each of the MDR's reported. In addition, I reviewed the results and assessments made by the Clinical Review Board.

A review of the MDR files determined that one MDR was filed 4 days after the reporting requirement of 30 days for Complaint/MDR #AA030093, refer to Exhibit #M4. The complaint was received on April 29, 2003 and the MDR was reported on 06/02/03, which is approximately four days after the 30 day reporting requirement, refer to Exhibit #M4 Page and Page

I informed Mr. Cornwell that the MDR was reported late and explained that the reporting requirement is 30 days from the day in which the firm was made aware of the event. Mr. Cornwell stated their initial assessment, based on the information provided at the time, indicated that the event was not reportable. I responded that the complaint was received on 04/29/03 from ERBE and that a representative of the company was also informed of the event by refer to Exhibit #M4 Page The company made their initial assessment for MDR reporting on Mr. Cornwell stated they received additional information from the doctor on and reassessed the event to report a MDR, so the 30 day reporting requirement should begin on I explained that the reporting requirement indicates that a MDR must be filed within 30 days of becoming aware of the event and that their own records indicate that attempts to contact were not initiated until I , refer to Exhibit #M4 Page

, stated that if company obtains additional information that suggests an event should be reported, the days counted towards the reporting requirement of 30 days begins when the new information is received. I responded that the 30 day reporting requirement begins when the company is made aware of the event and that it is the firm's responsibility to initiate efforts to obtain the information such as calling the physician involved in the case. The physician reported the incident on , but the company did not attempt to contact the physician until . refer to Exhibit #M4 Page 2. I explained that this was an issue that could be an observation placed on the FDA-483.

Mr. Cornwell stated they filed a MDR as soon as they obtained additional information. I explained that by waiting until to contact the reporting physician contributed to their delay in making an assessment.

Later on in the inspection period, I explained that the item would not be placed on the FDA-483 form, but it would be reported as an issue discussed with management. All other MDR's were submitted within the 30 day reporting requirement.

The two complaint records, in which a MedWatch form was received, were reviewed. The company conducted investigations and documented their rationale for not reporting the events. One MedWatch form was for a product not manufactured by Utah Medical.

For the specific records reviewed during this inspection, Medical Device Reports were filed, when necessary, and if a MDR was not submitted, the firm documented the results of the investigation and

rationale.

In addition, the company provided a memorandum, dated 10/03/03, in response to this observation, refer to Exhibit #M99.

OBSERVATION 7: Investigators Medina (E, F), Wilkins (A, B), and Jerndal (C, D, G) followed up on this observation.

Appropriate procedures have not been documented and followed for controlling environmental conditions.

Specifically,

A. Rev Microbial Bioburden Testing of Devices is unclear, in that it,

1. **does not state the required frequency of bioburden testing;**
2. **it does not state what actions to take when the "Results" show ; and,**
3. **lacks information on testing of caps, ports, and inner lumens of devices.**

CORRECTION:

Written by Investigator Wilkins.

An observation related to procedure Revision , Microbial Bioburden Testing of Devices, was identified and cited during the 2003 inspection because the procedure does not define the required frequency for bioburden testing.

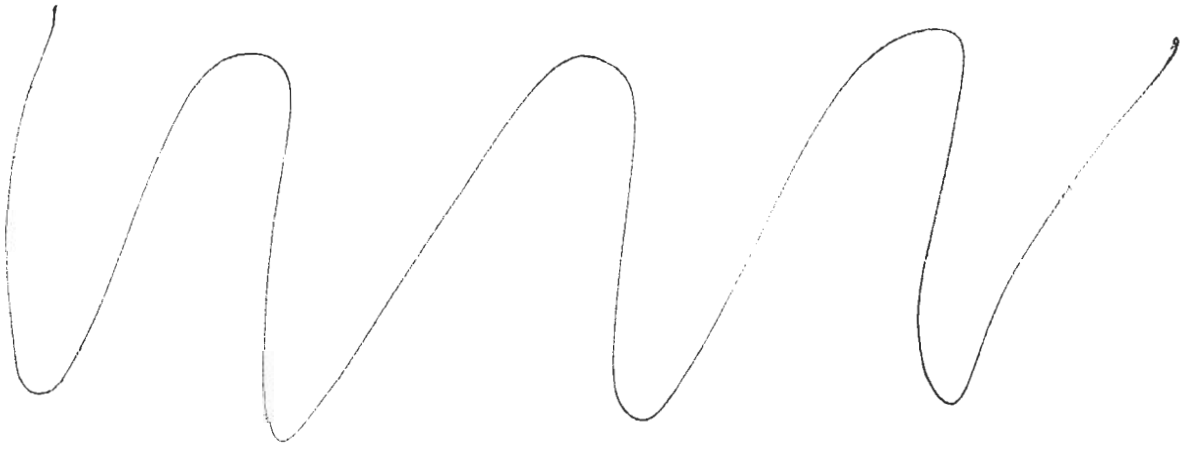
On 02/08/04, a review of the current procedure titled "Microbial Bioburden Testing of Devices", Document No. Revision , Revision Date , revealed that it was the same revision as cited in the observation, refer to Exhibit #M100. The Microbial Bioburden Testing of Devices procedure, Revision does not define the frequency of bioburden testing or reference another procedure. Although not referenced, during the review of the sterilization process, I also reviewed the Environmental Control and Monitoring procedure, Document No. Revision , Revision Date which defines the frequency of bioburden testing, refer to Exhibit #M101 Pages

A review of the revision history for the Environmental Control and Monitoring procedure revealed that under Change Proposal (ECR Number) No. , Revisior Revision Date procedure was :fer to Exhibit #M101 Page The testing frequencies were defined and included for the Environmental Control and Monitoring procedure, Document No. , Revision Revision Date

The previous inspection also identified an observation in which the Microbial Bioburden Testing of Devices procedure, Revision did not define or instruct on what actions must be taken when the bioburden results include spreaders, with a notation indicating the count is considered a minimum estimate due to swarming of certain colonies on the membrane.

During this inspection, Revision of the Microbial Bioburden Testing of Devices procedure was still in effect, refer to Exhibit #M100. A review of the Microbial Bioburden Testing of Devices and Environmental Control and Monitoring procedures revealed that the procedures do not define and instruct on how to interpret or handle results, which are identified as spreaders, for the bioburden population count on devices received from the contract testing laboratory.

When asked, stated they accept the results from the Contract Laboratory when He recommended I discuss the issue with I requested the Contract Laboratory's procedure addressing how the counts are reported when the plates include spreaders. obtained the procedure form provided Chapter 3, Aerobic Plate Count, from the FDA Bacteriological Analytical Manual (BAM), 8th Edition (Revision A)/1998, which the contract laboratory uses to indicate the level of microorganisms in a product, refer to Exhibit #M102. The section titled Spreaders, Section C.3, describes spreaders as follows:



The acronym listed above refers to the Aerobic Plate Count. Section D, of the procedure titled Computing and Recording Counts, includes instructions under subsection D.4 to report all plates with spreaders as SPR.

On 02/12/04, a meeting was held with [redacted] Ben Shirley, [redacted] and myself, Investigator Wilkins. When asked, [redacted] indicated that when a count of the bioburden population is reported on a plate that contains spreaders, it is because the Contract Laboratory Analyst believes the data and count to be an accurate representation. [redacted] explained that as a whole he feels the data is valid, but that they may not have done a good job in characterizing the spreaders in their documentation. [redacted] stated they now document in more detail the nature of the spreader and areas covered. [redacted] stated when spreaders occur the counts provided are an estimate and their new (revised) procedures alert the customer and recommend that they identify spreaders that are genus/species specific, re-sample, and retest any results obtained from plates containing spreaders. When asked, [redacted] confirmed that the [redacted] ' procedure was revised with the information provided during this meeting. I asked [redacted] what recommendations he would provide to Utah Medical if the bioburden count results were reported as estimates to Utah Medical due to spreaders. He responded that he would recommend that they re-sample and retest the product.

Next, I asked Mr. Shirley if Utah Medical intended to modify their procedure to include instructions to re-sample and retest when they received results that identified spreaders on the plates. Mr. Shirley indicated he would consider the need for modifying Utah Medical's procedure.

On two occasions we had follow-up discussions on the issue. I stated the observation concerning the procedure not instructing on how to handle results obtained from plates containing spreaders would be recited as an observation, because their procedure was not modified to instruct on the need to re-sample and retest product when bioburden count results are estimated from plates that contain spreaders. Mr. Shirley indicated that it should not be cited as an observation because [redacted] had modified their procedure and were only recommending to retest. He stated it was not required to re-test the product and the results from spreaders were valid. Mr. Shirley also alleged that I was misinterpreting and misrepresenting [redacted] comments. My response was that I was not misinterpreting or misrepresenting [redacted] s comments. To place the issue into context, I explained the reporting requirements outlined in the BAM procedure provided by [redacted] Mr. Shirley indicated they intended to modify their procedure to include instructions to retest when spreaders occur, but did not agree that it should be repeated as an observation cited on the FDA-483.

On 02/26/04, I informed Mr. Shirley and Mr. Cornwell that I would not include the issue as an observation, because a review of my notes documented that [redacted] had modified their procedure to recommend retesting prior to the initiation of this inspection. I also stated that the observation would not be repeated on the condition that Utah Medical proceeded with the revision of their procedure, because the procedure needed to indicate how results including spreaders would be handled at Utah Medical Products, Inc.

Later, Mr. Shirley provided the revised procedure, Microbial Bioburden Testing of Devices,

Revision Revision Date which included the following modification:

In addition, I reviewed the results of all the microbial bioburden testing of devices that were performed after All of the results for the product bioburden counts were reported as actual results and did not include any estimates based on spreaders.

Another observation cited during the previous inspection identified that the Microbial Bioburden Testing of Devices, Revision L, lacked information on testing of caps, ports, and inner lumens of devices.

On 02/12/04, I discussed this issue with He stated that the method and testing were described for each customer on Work Instructions, which are stored on their computer database. provided the following Work Instructions:

The Work Instructions include the specific methods used and instructions. For example, the Work Instruction sheet for the UP product describes the Test Method as follows, refer to Exhibit #M104:

-
-
-
-
-

In addition to following the Bioburden procedure, Document No. , Date the Work Instructions provide the information on the test method and instructions on the testing of caps, ports, and inner lumens of devices, refer to Exhibit #107 and Exhibit #'s 104-106, respectively. This issue is resolved as confirmed that the Work Instructions have been approved and were in place prior to the previous inspection.

The three observations within this section are either corrected or resolved based on additional information provided by Utah Medical Products, Inc. and

B. , Rev and the current titled, Bioburden, signed by John R. Smith does not specify which extraction method is to be used. out of bioburden tests reviewed revealed the extraction method was but this method has not been standardized and controlled in the procedure.

CORRECTION

Written by Investigator Wilkins.

This observation was cited because Utah Medical's procedure, Document No. Revision , and the Bioburden procedure, Document No. , does not specify which extraction method is to be used and/or the method has not been standardized and controlled in the procedure.

Prior to meeting with , I reviewed the Bioburden procedure, Document No. Date On 02/12/04, I discussed this issue with

[redacted] In addition to the procedure, he stated that the method and testing were described for each customer on Work Instructions, which are stored on their computer database. [redacted] provided the following Work Instructions:

[redacted]

The Work Instructions include the specific methods used and instructions. For example, the Work Instruction sheet for the [redacted] IUP product describes the Test Method as follows, refer to Exhibit #M104:

[redacted]

The Bioburden procedure, Document No. [redacted], Date [redacted], and Work Instructions provide information on the standardized test methods and instructions on the testing and are controlled, refer to Exhibit #107 and Exhibit #'s 104-106, respectively. This issue is resolved as

nfirmed that the Work Instructions have been approved and were in effect prior to the previous inspection.

C. Procedure, Environmental Control and Monitoring, is inadequate because,

1. **there is no justification for not sampling water at the extruder when a previous test report dated found and,**
2. **it does not include a diagram of the compressed air system identifying points of use and justification for why there is only one sampling point.**

Written by Investigator Jerndal. See this firm's response to the prior 483 Exhibit L10, Observation 7C.

D. Extruder procedures , Rev. , Extrusion Set-up , Extrusion Running Procedure and Extrusion Cleaning are inadequate due to the following observations made during extrusion molding o

1. **the upper cooling tray that tubing passes through had tan floating debris in it;**
2. **the lower cooling tray was uncovered, rusty, and had a film coating it. This water is recirculated for cooling tubing passing through the upper cooling tray;**
3. **the water control float had an empty cleaning bottle taped to it; and,**
4. **the take off conveyor was cracked with dark areas within the cracks.**

Written by Investigator Jerndal. See the firm's response to the prior 483 Exhibit L10, Observation 7D. The extrusion equipment was examined during this inspection. At the time the equipment was not being operated. However, equipment appeared to be cleaned and well maintained.

E. Permanent Equipment Assembly and Servicing Guidelines states that wrist straps or ankle straps must be used for Electrostatic Discharge control (ESD)

1. **on the ESD continuous monitor used in association with the wrist strap in the room at the work station location was not visible to the operator,**

although the equipment was in use. On 3/6/03, the H Mat light was not visible; and,

Written by Investigator Medina. This item was observed to have been corrected. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 7E, Page 300 contains information associated with the firm's response to this issue. The response indicates that the monitor was moved to a visible location on This was not able to be observed during this inspection due to lack of time.

2. **on 3/6/03, the ESD continuous monitor in the room, at work station behind the work station and closest to the room exit corridor, was observed to be mounted below the table top such that an operator standing or sitting at the work bench could not see the H Mat, L Operator, or OK system lights.**

Written by Investigator Medina. This item was observed to have been corrected. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 7E, Page 300 contains information associated with the firm's response to this issue. The response the lights at this station can be easily checked/viewed during use. This was not able to be observed during this inspection due to lack of time.

F. **Procedure , Rev. , Permanent Equipment Assembly and Servicing Guidelines, Section , states that evidence of last ESD equipment qualification must be at or near the work station. Qualification documentation was not observed at or near any work station in the room.**

Written by Investigator Medina. This item was observed to have been corrected. Exhibit L117 is "TRAINING DOCUMENT" number Revision , dated entitled "PERMANENT EQUIPMENT ASSEMBLY AND SERVICICNG GUIDELINES". Exhibit L118 is the same procedure as mentioned above and is the current revision dated and is attached for reference. Section Page has been ast
No deficiencies were noted.

G. **The Instrument Calibration Procedure, used by calibration of the laser micrometer used in extrusion, does not require the technician to denote on the Certificate of Calibration which test method was used**

Written by Investigator Jerndal. See this firm's response to the prior 483, Exhibit L10 Observation 7G. Exhibit R120 is a copy of the most recent Certification of Calibration for the Zumbach Laser Mike ID #01125.

OBSERVATION 8: Investigator Jerndal followed up on this observation.

Process control procedures that describe any process controls necessary to ensure conformance to specifications were not established.

Specifically,
There are inadequate process controls established for the water system as evidenced by the following:

1. **As of , no blueprints or diagrams were available on the water system showing: piping throughout the firm, valve locations, points of use, sampling points, mixing hookups, water storage tank, no incoming water specification, and no extrusion water quality specifications.**
2. **There are no chlorine specifications and no mixing records for water.**
3. **Rev , dated for Acceptability of Handwashing Water and , Rev , dated , Acceptability of Handwashing Water show water samples were only collected from The test procedure is inadequate in that, there are locations for cleanroom handwashing basins and only were sampled.**

Written by Investigator Jerndal. See this firm's response to the prior 483, Exhibit L10, Observation 8. Also see discussion under prior 483 Observations 8.2, 8.3 in this inspection report.

OBSERVATION 9: Investigator Medina followed up on this observation.

Certain inspection, measuring, and test equipment is not suitable for its intended purposes or capable of producing valid results.

Specifically, the Qualification of the Final Tester (used to perform final device testing on , dated

a. **does not include the use of devices with "known" defects to challenge the test equipment's ability to detect said defects;**

b. does not define the acceptable value of standard deviations; and,

c. does not qualify the test equipment to test for "Electrical" defects, an attribute that the tester is currently being used to evaluate.

Written by Investigator Medina. This item was observed to have been corrected. Exhibit L10 contains the firm's response to the FDA-483 dated 3/12/03. Section 9, Page 337 contains information associated with the firm's response to this issue. A summary is as follows:

a) Known Defects: If there is a leak between the catheter and tester, the tester will not function. The test report and results included leak testing that determined the tester is capable of maintaining a proper seal. The firm determined that [redacted] did not need to be conducted.

b) Acceptable standard deviation: The firm's DMR states that the sensitivity deviation on the final product can be between [redacted] In actual production, the firm tests to a range [redacted] According to Mr. Shirley, this provides a safety margin of [redacted] The highest deviation listed within the [redacted] test data is [redacted]

c) Electrical defects: Electrical defects are defined by the firm as "...if the equipment receives a value that is within specification, the unit is accepted. If the value is outside the range, it is rejected. If the catheter returns no value it is obvious that there is some 'electrical defect'...

Exhibit L116 is "TEST PROTOCOL" entitled "TEST PROTOCOL" entitled "QUALIFICATION OF [redacted] FINAL TESTER", number [redacted] Revision [redacted] dated [redacted] which describes the qualification of the final tester for [redacted] This qualification addressed the issues as follows:

[redacted]

OBSERVATION 10: Investigators Wilkins and Jerndal followed up on this observation.

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically,

1. **Complaint for the device was received for a customer complaint of a burning sensation. The complaint evaluation revealed that the measured on the unit was and the was although the specification for both is . The complaint was closed with the comments , "No further action required". The NCMR associated with this returned unit and complaint indicates that the unit was refurbished and returned to marketing stock. The DHR showed test results of and did not meet the DMR specification of The DHR was inadequate in that it did not contain documentation of refurbishing steps taken and therefore, there is no assurance that the device met the requirements of the DMR.**
2. **IUP devices that do not contain a valve, and were manufactured between were manufactured under a Request for Deviation/Waiver, The D/W called for these devices to have the of checked The D/W does not state or refer to any established acceptance criteria for this check.**

Written by Investigator Jerndal See current FDA-483 item number 7 and the Objectionable Conditions section of this report.

CORRECTION

Written by Investigator Wilkins.

During the current inspection, all three of the investigators, Medina, Jerndal, and myself, reviewed Device History Records. During the 2003 inspection, an observation was cited because some of the device history records did not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

During the current inspection, Investigator Medina, Investigator Jerndal, and myself (Investigator Wilkins), reviewed Device History Records (DHR's). I, Investigator Wilkins, reviewed the sterilization process cycle records as part of the DHR review. The following sterilization cycle processing records were reviewed:

STERILIZATION PROCESS CYCLE RECORDS (DHR'S)

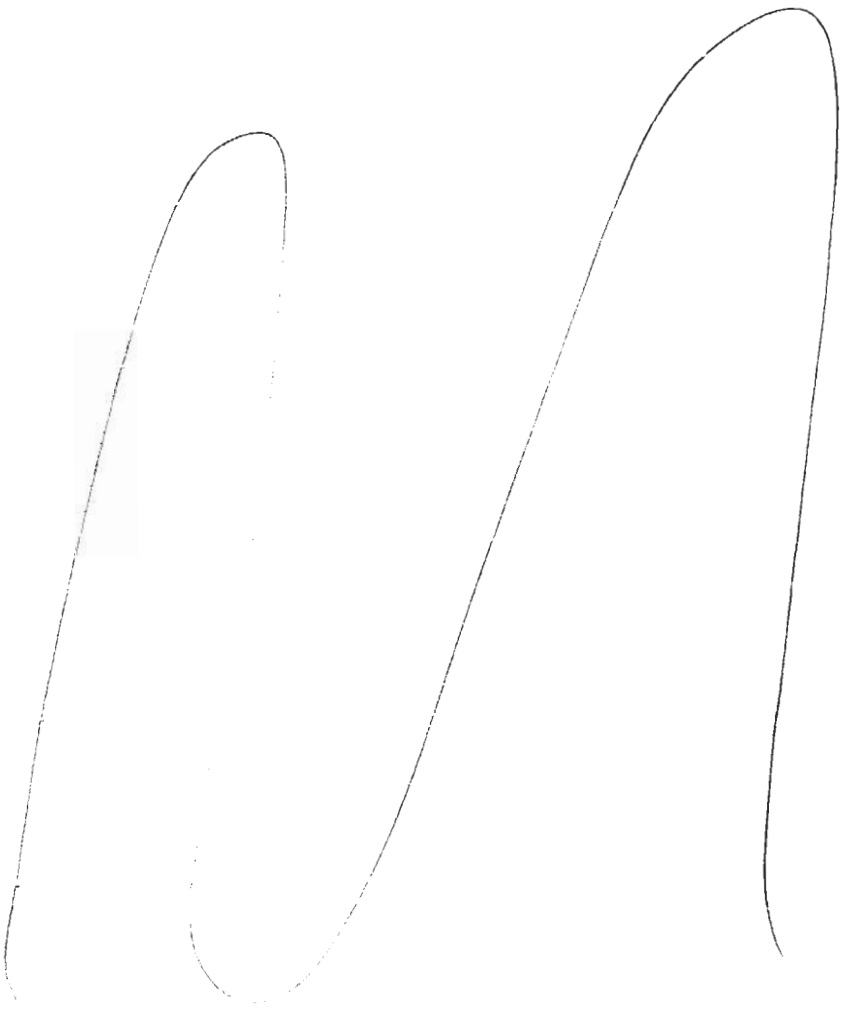
The sterilization cycle process/retort records identified and included documentation of the product lot history numbers sterilized. During the review of the sterilization process cycle records (process/retort records), I selected for review the lot history records identified below.

I, Investigator Wilkins, reviewed 29 DHR's lot history records for various devices because they were selected for review in relation to the sterilization cycle records instead of a specific device. The following DHR's were reviewed for devices manufactured between the period of

DEVICE HISTORY RECORDS

LOT NUMBER	PRODUCT NUMBER	PRODUCT NAME

LOT NUMBER	PRODUCT NUMBER	PRODUCT NAME



The sterilization cycle records (process/retort records) and related DHR's reviewed during this inspection included and documented the acceptance criteria.

OBSERVATION 11: Investigator Wilkins followed up on this observation.

Procedures for verifying that design output meets design input were not complete.

Specifically,

A. Test Protocol, [redacted] IUP [redacted] Test used to qualify the [redacted] compared to one another for all devices tested. Therefore, the firm failed to have adequate procedures to ensure that design outputs met the requirements of design inputs.

Written by Investigator Wilkins.

CORRECTION

The previous inspection included an observation indicating that the firm failed to have adequate procedures to ensure that design outputs met the requirements of design inputs because Test Protocol, [redacted] did not define what the acceptable pressure reading should be for the functionality test, rather the measured values were compared to one another for all devices tested.

I, Investigator Wilkins, reviewed the IUP Functionality Test Protocol, Document No. [redacted], refer to Exhibit #M108. The Test Protocol, Document [redacted] includes the following acceptance criteria for the "pressure test" cited under this observation:

[redacted]

In addition, I reviewed the Qualification of the [redacted] for [redacted] Test Report, Document No. [redacted] refer to Exhibit #M86. The Functionality section, Section [redacted] of the Test Report [redacted] describes the purpose of the "pressure test" as follows:

[redacted]

The acceptance criteria for the "pressure test" is included under the Acceptance Criteria section, Section [illegible] of Test Report No. [illegible] and is defined as follows:

[illegible]

On 03/01/04, I discussed the Test Protocol No. [illegible] and Test Report No. [illegible] with Mr. Ben Shirley. When asked, he described the "pressure test" as an electrical function test and not a test to measure the accuracy of the sensor. The test is performed to verify that fluids do not seep into the device and affect the transducer. The acceptance criteria, as defined in the protocol and test report, is appropriate for the intent of the test because if any fluids enter the device, the fluid would immediately affect the transducer causing the erratic pressure readings.

Additional information provided by the company clarified the issue.

In response to the observation cited during the 2003 inspection, the company provided a Memorandum, dated [illegible], for this observation, refer to Exhibit #M109.

B. Test Report, [illegible] Qualification of the [illegible] for [illegible]. The TR functionality tests were performed according to [illegible] Neither the TP nor the TR defines

1. which lots of finished product will be used in the qualification; or,

2. what the acceptable pressure reading should be for the functionality test; it only states what the acceptable deviation value is from baseline.

Therefore, the firm failed to provide objective evidence that the design outputs met the requirements of the design inputs.

CORRECTION

Written by Investigator Wilkins.

An observation was cited during the 2003 inspection documenting that Test Protocol No. and Test Report did not reference or identify the lot numbers of finished product used in the qualification; or, what the acceptable pressure reading should be for the functionality test; it only states what the acceptable deviation value is from baseline.

On 02/26-27/04 and 03/01-02/04, I, Investigator Wilkins, reviewed the IUP Test Protocol, Document No. , and Qualification of the for Test Report, Document No. refer to Exhibit #M108 and Exhibit #M86, respectively.

The Qualification of the for Test Report, documents that the product test samples were processed through three ethylene oxide cycles and then placed in the environmental chamber for two weeks per procedure refer to Exhibit #M86 Page The current leak test, functionality test soak test, and pull test were performed on the product test samples, refer to Exhibit #M86 Pages

I reviewed and verified the raw data and records associated with Test Report which included the following:

- DHR Extra Process Work Order
- DHR EPWO refer to Exhibit #M87
- Sterilization Cycle Process/Retort
- Sterilization Cycle Process/Retort
- Sterilization Cycle Process/Retort

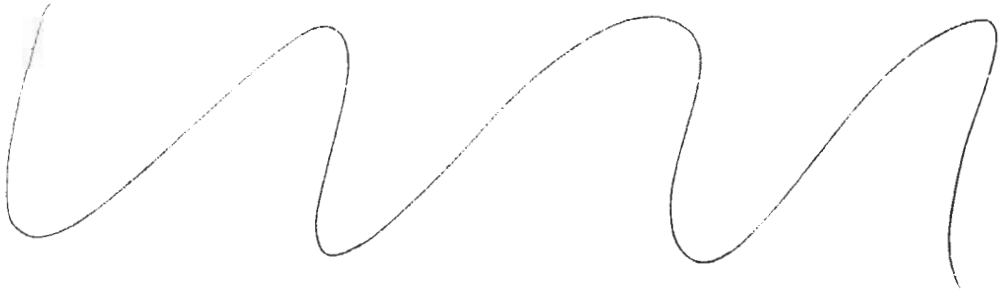
The test samples were manufactured under DHR lots, one for product test samples with the and for the product test samples with the , and each DHR lot was exposed to

Next, the product test samples were placed in the environmental chamber for per procedure to Exhibit #M79. I verified data for the environmental chamber by reviewing the Environmental Chamber Log.

In addition, I verified the raw data for the current test, functionality test, and pull test. The raw data is maintained in Change Proposal and the Appendices section, Section , of Test Report includes a reference to refer to Exhibit #M88 and Exhibit #M88 Page respectively.

Section of the Test Report 4 describes the following:

The raw data for the functionality test is located in , refer to Exhibit #M88 Page . The results after the worst case were as follows:



e in
to

The test results documented in Test Report No. did not include failures after exposure to in the environmental chamber, and functionality test worst case

On 03/01/04, I discussed the Test Protocol No. and Test Report with Mr. Ben Shirley. When asked, he described the "pressure test" as an electrical function test and not a test to measure the accuracy of the sensor. The test is performed to verify that fluids do not seep into the device and affect the transducer. The acceptance criteria, as defined in the protocol and test report, is appropriate for the intent of the test because if any fluids enter the device, the fluid would immediately affect the transducer causing the erratic pressure readings.

Although the Test Protocol and Test Report do not directly reference the DHR's (lot numbers), the company has the data and lots associated with the Test Report. I verified the lot histories and sterilization cycle histories. I explained to Mr. Shirley the importance of referencing and/or documenting data related to any testing and/or validation because the information can then be associated with the test protocol and test report.

The observation was also cited for the not defining the acceptable pressure readings for the functionality tests and that it only states what the acceptable deviation value is from baseline. The purpose of the test was to verify that fluid would not seep into the device during a worst case

simulated use test. Based on the additional information obtained from the company, this observation is resolved.

In response to the observation cited during the 2003 inspection, the company provided a Memorandum, dated [redacted] or this observation, refer to Exhibit #M109.

OBSERVATION 12: Investigator Wilkins followed up on this observation.

Design validation did not ensure that devices conform to defined user/patient needs and intended uses.

Specifically, while the firm has performed accelerated aging testing for devices, real time shelf life testing has not been implemented to confirm the results of the accelerated aging testing. Therefore, there is inadequate design validation to support the firm's intended use of a five year expiration date specifically on [redacted] devices.

CORRECTION

Written by Investigator Wilkins.

I, Investigator Wilkins, inquired if the company followed any standards for packaging validation. Mr. Shirley stated he would check with [redacted] to verify if a packaging standard is referenced or followed by the company. During my review of documents, I determined the company follows the requirements of ISO 11607 – Packaging for Terminally Sterilized Medical Devices, 1st Edition, 1997-02-15. The standard indicates that the real time packaging studies are recommended, but not necessary if accelerated packaging studies were performed and documented.

A review of the firm's 510(k)'s indicated that there was no requirement to conduct real time packaging studies. The firm follows the ISO 11607 standard for terminally sterilized medical devices and conducted accelerated aging studies to verify the shelf-life of the packaging materials and products. The accelerated aging studies are supplemented by real time packaging studies to verify the expiration date.

I reviewed the Accelerated Aging and Package Integrity Test, Protocol No. [redacted] and Final Report for Accelerated Aging and Package Integrity Test, Laboratory No. [redacted] to verify the accelerated aging tests conducted on packaging materials to evaluate the barrier properties of the packaging materials following a [redacted] accelerated aging period. The results indicate that the

packaging materials demonstrate a sterile barrier properties following an extreme bacterial aerosol challenge after exposure to a accelerated aging.

In addition, to verify functionality testing of a product after accelerated aging tests, I requested any information related to the Real Time Packaging Integrity Test Report, efer to Exhibit #M75. A review of Test Report No. evealed that the Appendix section referenced Change Proposal refer to Exhibit #M75 Pages A review of included the testing raw data from Test Report A few sections of were obtained, refer to Exhibit #M76.

Test Report referenced the Testing procedure, refer to Exhibit #M75 Page I reviewed the , Document No. which outlines the pressure testing of packaging seals, refer to Exhibit #M77. In addition, the following procedures referenced or followed during the execution of the Real Time Packaging Integrity Test included the following:

I requested the device history record (DHR) for the products manufactured for the testing described in the Real Time Packaging Integrity Test Protocol and Report. Mr. Shirley provided DHR . A review of the information documented in DHR . verified the documentation was relevant to the test protocol and test report.

In addition, ndicates the test articles were exposed to and stored at ambient temperature and humidity for refer to Exhibit #M75 Page A review of the Process/Retort Cycle records referenced in DHR , revealed the test articles were exposed to

Since the company relies on accelerated aging tests to verify the shelf-life of the product, I decided to verify the accelerated aging test data for the The Qualification, Document No. includes the accelerated aging tests for the product among other elements included in the testing, refer to Exhibit #M78. Section , titled Shelf Life Processing, of the Redesign Qualification Test Protocol, Document No. requires the following processing steps for the accelerated aging, refer to Exhibit #M78 Page

The Environmental and Accelerated Aging Tests procedure, Document No. [redacted] scribes and defines the environmental test parameters and accelerated aging requirements, refer to Exhibit #M79.

The [redacted] Qualification Test Report, Document No. [redacted] documents the results to qualify the dimensional modifications made to the device, [redacted] refer to Exhibit #M80. Change Proposal [redacted] as initiated to allow for [redacted] for the product.

The Test Report No. [redacted] documents the following:

[redacted]

I reviewed the raw data beginning with the Extra Process Work Order [redacted] the [redacted] product manufactured between [redacted] refer to Exhibit #M81. The DHR [redacted] includes a notation that the product be returned to the [redacted] refer to Exhibit #M81 Page 7.

Next, I verified that the product was exposed to [redacted] I reviewed the following sterilization process cycle records:

[redacted]

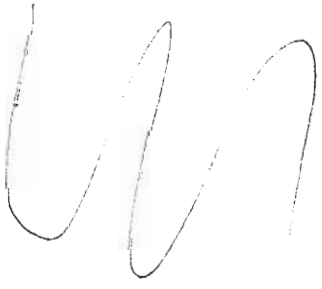
The process/retort sterilization cycle records did not specifically reference the but engineering box containing the products of was labeled and identified with the engineer in charge of the product and dates. The engineer name and dates, identified with the engineer box documented within the sterilization cycle records, provided the linkage to the product manufactured under DHR

Next, I reviewed the data related to the of environmental aging performed per procedure The Environmental Chamber Log revealed that the product samples for were placed in the environmental chamber for between the dates The product was placed in the environmental chamber for under the conditions described under the Environmental and Accelerated Aging Tests procedure, Document No. efer to Exhibit #M79 Page

After reviewing the data for the environmental aging test, I reviewed the data for the accelerated aging tests. The product samples were placed in an oven at simulate a shelf-life. The Oven Using Control Log documents that the product samples were placed in the oven from

Once the review of the raw data associated with the shelf life processing tests was completed, I reviewed the product inspection and test data as outlined in Section Inspection and Testing section, of the Qualification Test Protocol, Document No. efer to Exhibit #M78 Page

The test was performed according to and procedure, Document No. he visual inspection and test data is included in Test Report No. under the section titled "Final Qualification Test Results refer to Exhibit #M80 Pages The pull test results in Test Report nder the section titled "Final Qualification Pull Test Results ocumented that samples from each group were pulled at the , refer to Exhibit #M80 Pages The pull test results were as follows:



PURGED

The Conclusion section, Section — of the — Qualification, Document No. —, concludes that the base plate is released for production and distribution as qualified for —

In addition, the raw data for the test results documented in Test Report No. — was reviewed to ensure the data reflected the same information as summarized in the final report. The data was verified. In order to verify the results of the pull test, I reviewed the Design Specification, Document No. — refer to Exhibit #M82. The bonded connection strength specification listed under Section — is defined as the bond connection strength must not break or crack at less than — of force. The pull strength test results in Test Report No. — demonstrate that the bond connection strength is greater than — refer to Exhibit #M80 Pages —

As verified during this inspection and as noted in the 2003 observation, the company has conducted accelerated aging tests for packaging. Based on further clarification, this observation has been resolved. In addition, the company is currently conducting real time packaging tests.

As a response to the 2003 observation, the company provided a Memorandum, dated 02/13/04, refer to Exhibit #M110.

OBSERVATION 13: Investigator Wilkins followed up on this observation.

Procedures were not established for the validation or verification of design changes before their implementation.

Specifically,

1. **The currently used Test Protocol, — unctionality Testing calls for — to be completed periodically throughout a — period —. The TP could not have been completed as written. The procedure is not current in that — is no longer being used and the TP does not address the current —**

2. **Test Report, —) for Qualification of the — reports that functionality testing was done per — However, — calls for the devices to be —, while the TR states the devices are to be —**

The firm did not follow their own procedure and the TP and the TR are in contradiction to one another.

CORRECTION

Written by Investigator Wilkins.

An observation was cited during the 2003 inspection documenting that Test Protocol, Functionality Testing calls for of devices and a o be completed periodically throughout a but the TP could not have been completed as written. Also, the procedure is not current in that is no longer being used and the TP does not address the current

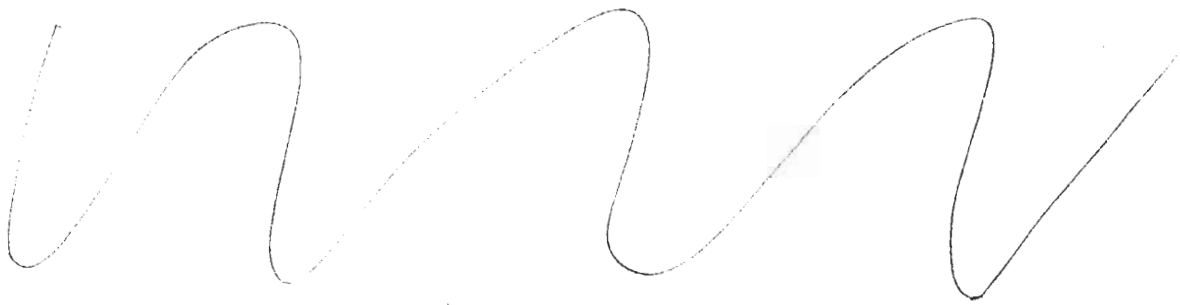
On 02/26-27/04 and 03/01-02/04, I, Investigator Wilkins, reviewed the Functionality Test Protocol, Document No. and Qualification of the refer to Exhibit #M108 and Exhibit #M86, respectively.

A review of the protocol describes a testing method consisting of the following:

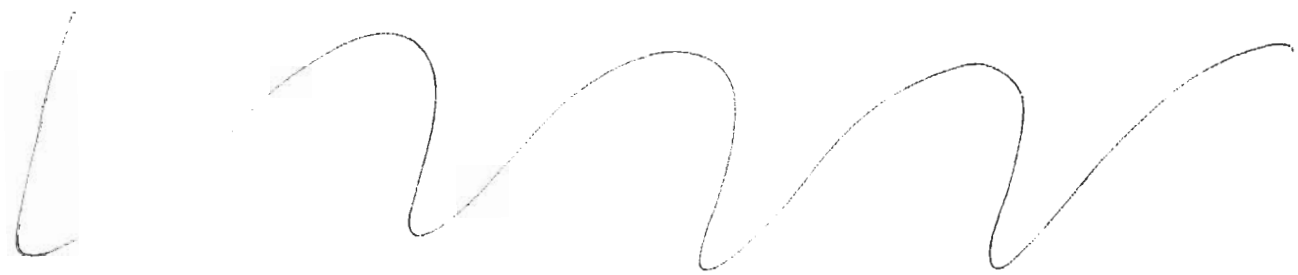
Sectio of the Test Protocol , instructs to periodically remove the units during the period and perform steps and when the test is complete, refer to Exhibit #M109 Page Based on the information contained in the protocol description, the test steps involving the

The company provided a Memorandum, dated explaining that the protocol was an established protocol, which had a typographical error, refer to Exhibit #M111. On 02/26/04, Mr. Ben Shirley explained the Test Protocol, Revision document contained a typographical error and should have instructed to "perform steps

The company revised the Test Protocol No. [redacted] under Change Proposal (CP) [redacted] by modifying the following information in [redacted]



Steps [redacted] provide the same instructions as included in revision [redacted] of this test protocol:



The revised [redacted] Functionality Test Protocol, Document No. [redacted] corrects the typographical error by referencing the appropriate test sections to repeat, refer to Exhibit #M112.

In addition, the observation cited during the 2003 inspection documented that Test Protocol [redacted] described a [redacted] nethod for the devices, but Test Report No. [redacted] documented [redacted]
The observation described that the firm did not follow their own procedure and the TP and the TR are in contradiction to one another.

A review of the Qualification of [redacted] s Test Report, Document No. [redacted] ocuments that the product test samples were processed through [redacted] per procedure [redacted], refer to Exhibit #M86 Page [redacted] The current [redacted] test, [redacted] functionality test soak test, and pull test were performed on the product test samples, refer to Exhibit #M86 Pages [redacted]

I reviewed and verified the raw data and records associated with Test Report [redacted] which included the following:

The test samples were manufactured under two DHR lots, one for product test samples with the ~~ and one for the product test samples with the ~~, and each DHR lot was exposed to ~~

Next, the product test samples were placed in the environmental chamber for ~~ per procedure ~~, refer to Exhibit #M79. I verified data for the environmental chamber by reviewing the Environmental Chamber Log.

In addition, I verified the raw data for the current ~~ test, ~~ r functionality test, and pull test. The raw data is maintained in Change Proposal (CP) ~~ and the Appendices section, ~~ includes a reference to ~~, refer to Exhibit #M88 and Exhibit #M88 Page ~ respectively.

The test results documented in Test Report ~~ did not include failures after ~~ ; functionality test worst case ~~ conditions.

The company has Test Protocols that are used for numerous tests and studies. Inadvertently, the Test Protocol was not revised when the company changed the sterilization method fron ~~ ~~ The data and sterilization procedures in effect at the time document the method of sterilization was ~~ The company has updated the test protocol to correct this issue, refer to Exhibit #M112.

The revised ~~ Functionality Test Protocol, Document No ~~ ~~, corrects the error by modifying the text to allow for the ~~ efer to Exhibit #M112

In addition, the company provided a Memorandum, dated ~~ explaining that the sterilization method used for production was ~~ so the protocol was modified to correct the sterilization method by instructing to sterilize with the same method as used for the production runs, refer to Exhibit #M111.

OBSERVATION 14: Investigator Wilkins followed up on this observation.

The design was not validated using production units under actual or simulated use conditions.

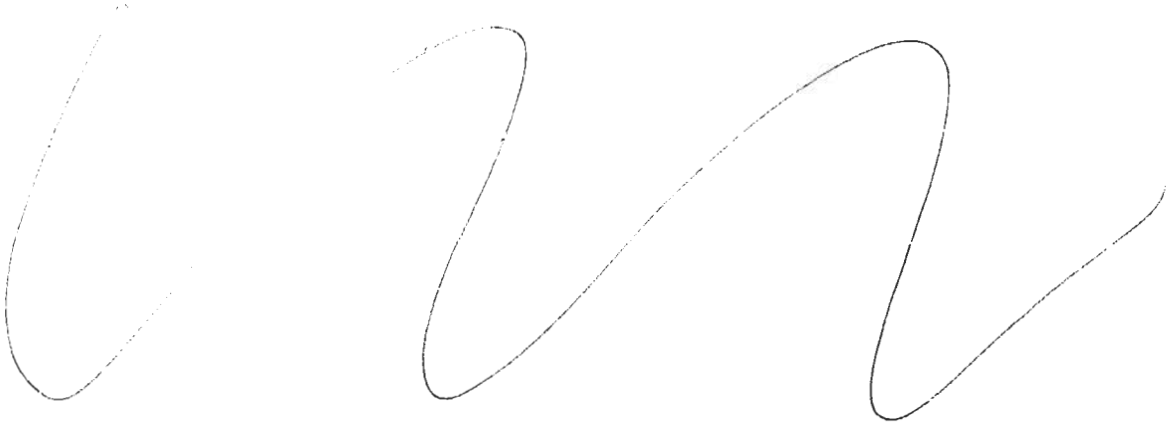
Specifically, Test Protocol, [redacted] Qualification of a [redacted] do not evaluate shipping stresses on the new packaging after accelerated aging.

CORRECTION

Written by Investigator Wilkins.

On 03/01/04, I, Investigator Wilkins, reviewed the Qualification of a [redacted] Test Protocol, Document No. [redacted], and Qualification of a [redacted] est Report, Document No. [redacted] refer to Exhibit #M113 and Exhibit #M114.

The Physical Package Performance Testing (Shipping Test) section, Section [redacted] of the Test Protocol No. [redacted] instructs to perform the shipping test as follows:



On 03/01/03, the Test Protocol [redacted] and Test Report [redacted] were reviewed with Mr. Shirley. Mr. Shirley stated the company conducts the shipping stress test right after product sterilization to simulate their actual distribution process of sterilizing the product and then shipping the product to customers.

In addition, I verified the data and results documented in the Qualification of a [redacted] : Test Report, Document No. [redacted], refer to Exhibit #M114. The following data, records, and results were reviewed to verify the results summarized in the Test Report [redacted]

The raw data for the accelerated aging and shelf-life results are maintained in the Design History File (DHF). The company has the testing data available for review. After discussion with the

company and additional information provided, the issue is resolved as it is not necessary to perform the accelerated aging prior to performing the shipping tests. The firm's rationale is that the shipping tests they performed simulate their routine practices of shipping the product after it has been sterilized.

On 02/23/04, the company provided a memorandum, dated 02/13/04, in response to the observation cited in 2003, refer to Exhibit #M120.

OBSERVATION 15: Investigator Jerndal followed up on this observation.

Appropriate design, construction, placement, and installation of manufacturing equipment have not been ensured.

Specifically, on ——, extrusion molding equipment was observed during operation with the following equipment modifications for use:

1. **tape was observed at the exit of the upper water tray, around the back of the extrusion nozzle;**
2. **plastic tubing was attached to the lead-in side of the ——————, and extrusion tubing was running over and in direct contact with the straw; and,**
3. **tape was used to attach extensions to the side guards on the take off conveyor where tubing exits the cutter onto the conveyor belt.**

Written by Investigator Jerndal. See this firm's response to the prior 483, Exhibit L10, Observation 15. The extrusion molding equipment was not observed operational during this inspection, however, it did appear to be clean and well-maintained.

OBSERVATION 16: Investigators Medina (C, D, E), Wilkins (B), and Jerndal (A) followed up on this observation.

Schedules for the adjustment, cleaning, and other maintenance of equipment were not established and implemented.

Specifically,

A. **There is no preventative maintenance plan for, nor documentation of, preventative maintenance being performed for the ——— used to measure tubing diameter on the extrusion line, although the instruction manual for the equipment calls for cleaning the windows ——————— The**

equipment was observed in use on 3/4/03.

Written by Investigator Jerndal. See this firm's response to the prior 483, Exhibit L10, Observation 16, RE: 16A. According to Mr. Shirlev, the extrusion/injection molding manufacturing area is maintained as a class [redacted] controlled environment and that their environmental monitoring typically achieves class [redacted] outcomes. The molding manufacturing area was examined only when the extrusion molding was not underway, however, a number of injection molding operations were in progress. The general manufacturing area appeared to be clean and orderly, and there was no visible dust or fumes observed.

B. The schedule for preventative maintenance of the [redacted] Packaging machine used in packaging IUP devices, was not complete in that it did not identify, specifically, all the areas of the equipment that require maintenance according to the equipment operator's manual. The PM does not refer to the operator's manual.

Correction

Written by Investigator Wilkins.

This observation has been corrected. I, Investigator Wilkins, reviewed the [redacted] packaging machine, [redacted] and verified the preventive maintenance schedule included all the required maintenance activities. In addition, the quarterly preventive maintenance records were reviewed and all the necessary maintenance activities for: [redacted] were performed, refer to Exhibit #M121 and Exhibit #M122, respectively.

On 02/23/04, the company provided a Memorandum, dated 02/17/04, to us in response to this observation cited in 2003, refer to Exhibit #M123.

C. The schedule for preventative maintenance of the Static Control Mats used in [redacted]

1. is not specific as to the areas of the mats that are calibrated;

Written by Investigator Medina. This item was observed to have been corrected. Mr. Shirley stated that the ESD mats are calibrated per the manufacturer's recommendations found as Exhibit L119 [redacted]

Page

Figure indicates the surface groundable points on the ESD installed surface.

Exhibit L120 is "CHANGE PROPOSAL" numbe in which the description of the change is to change The CP

"

2. which specific mats are tested on each quarterly PM;

Written by Investigator Medina. This item was observed to have been corrected. Exhibit L121 is a preventive maintenance (PM) work order for static control mats This document indicates that static control mats have PM performed on them. Mr. Shirley stated that according to this PM indicates that all mats are to be tested , therefore, there is no need for the firm to specify which ESD mats should be tested.

3. does not define that a surface inspection of the mat should be conducted; although, mats observed in the were found to have burns, nicks, cuts and holes in the ESD mat surface; and,

Written by Investigator Medina. This item was observed to have been corrected. Mr. Shirley stated that ESD mats are utilized within the production area and normal surface wear is expected. Additionally, he stated that preventive maintenance is conducted upon the mats on a quarterly basis to ensure that the mats are performing according to the established specifications. No visual appearance specification exists for the ESD mats currently being utilized by the firm.

4. PM work order oes not indicate that the PM was completed although the work order was signed and closed by

Written by Investigator Medina. This item was observed to have been corrected. The PM was corrected in and is found within the firm's response to the previous FDA-483 (Exhibit L10, Page 398). Exhibit L121 is a representative example of a preventive maintenance (PM) work order dated for static control mats. No deficiencies were noted.

D. Procedure equires tacky mats located at various room entrances to be changed daily and whenever necessary. On and

— tacky mats were observed to be dirty, outside of cleanrooms and/or inside the room. There is no documentation that the tacky mats are being changed daily or whenever necessary as required by the procedure.

Written by Investigator Medina. This item was observed to have been corrected. Procedure number ——— is found within the firm's response to the previous FDA-483 (Exhibit L10, Section 16A-E, Pages 400 - 409). Section — of this procedure addresses the maintenance of tacky mats at the entrances of rooms on a — basis. The firm contends that the procedure does not require that the changing of tacky mats be documented. During several visits to the production areas, the tacky mats were observed to be clean and appeared to have been changed routinely.

E. — Cleaning Log for Production Areas, Manufacturing — as not completed for the ——— , per ——— Housekeeping.

Written by Investigator Medina. This item was observed to have been corrected. Procedure number ——— is found within the firm's response to the previous FDA-483 (Exhibit L10, Section 16A-E, Pages 4 ——— states that ——— Exhibit L122 are the —Cleaning log for Production areas, Manufacturing ——— — which document these — cleaning activities between ——— . No deficiencies were noted.

OBSERVATION 17: Investigator Jerndal followed up on this observation.

There is incomplete documentation of the equipment identification for measurement equipment.
Specifically, the ——— ., Certificate of Calibration, test No. — for calibration of the ——— n use on the extruder, contained the incorrect equipment ID No. ———) and the incorrect model number ———

Written by Investigator Jerndal. See this firm's response to the prior 483, Exhibit L10 Observation 17. Exhibit R120 is a copy of the most recent Certification of Calibration for the ———

OBSERVATION 18: Investigator Medina followed up on this observation.

Documents were not reviewed and approved by the individual designated in document control procedures.

Specifically, an untitled document being used for calibration of the ESD system, which begins as [redacted], has not been made part of the controlled document system by review and approval.

Written by Investigator Medina. During a review of procedures, records, documentation, and data which occurred during this inspection, no evidence was observed to support that these aforementioned documents were not reviewed and approved by the individual designated in document control procedures.

OBSERVATION 19: Investigator Medina followed up on this observation.

Quality audits did not verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, Procedure, [redacted], is not adequate to describe how the audit plan is to be developed to ensure effective coverage of objectives. There is inadequate description of how to develop the audit plan. For example, the Corrective and Preventive Action System audit examined one CAR, [redacted] and a product recall. [redacted] This would not be enough information to determine the effectiveness of the firm's ability to meet all of the requirements of the corrective and preventive action system.

Written by Investigator Medina. This item was observed to have been corrected. Several procedures associated with internal audits have been revised since the previous inspection. A summary is as follows:

EXHIBIT	INTERNAL AUDIT DOCUMENT
L123	[redacted]
L124	
L125	
L126	
L127	

	FORM"
L128	INTERNAL AUDIT PLAN assigned audit of "Corrective & Preventive Action"; Page ✓ addresses numerous quality records reviewed including CARs (corrective action requests/reports).

EXHIBITS AND SAMPLES COLLECTED

Written by Investigator Medina.

One documentary sample (DOC 68796) was collected to document the manufacturing, ——— sterilization, and interstate shipment of a finished IUP medical device and associated deviations from the Quality System Regulation. A Memo to accompany DOC 68796 was prepared by Investigator Michael Goga to further document interstate commerce.

INVESTIGATOR LORI A. MEDINA EXHIBITS:

Exhibit L1: Daily inspectional summaries were audio tape recorded as Mr. Cornwell requested to tape record these meetings. The FDA copies of these tape recorded meetings is found as Exhibit L1 (attached to the original EIR only)

Exhibit L2: UTMD current 2004 registration with FDA as a medical device manufacturer, contract manufacturer, specifications developer, repacker/relabeler, and initial distributor

Exhibit L3: A current organizational chart (no individual names are included within this chart as Ben Shirley, Quality Manager, stated that it is against the firm's policy to provide individual names of firm employees).

Exhibit L4: A current QUALITY MANUAL.

Exhibit L5: A current floor plan of the facility.

Exhibit L6: Certificate of Registration of Quality System to ISO 13485:1996 under CMDCAS and I.S EN ISO 9001:1994. ——— provided said certification; Certificate Number ——— Registration Date ———; Remains valid until ———

Exhibit L7: Attachment 1 to Certificate number ——— which includes the scope and date of the audit (———

Exhibit L8: Certificate of Registration of Quality System to I.S. EN ISO 13485:2000 (based on and including ISO 9001:1994). [redacted] provided said certification; Certificate Number [redacted] Registration Date [redacted] ; Remains valid until [redacted]

Exhibit L9: 2002 UTMD Annual Report

Exhibit L10: The firm's response to the previous FDA-483 (dated 3/12/03) which was drafted, compiled, and provided to the current Investigator team during the current EI on 2/23/04. Exhibit L10a is the firm's cover letter dated 4/11/03 sent to the FDA Denver District Office from Mr. Cornwell in response to the FDA-483 issued to the firm on 3/12/03.

Exhibit L11: Representative promotional materials were obtained during the current inspection and a summary is as follows: **LABOR AND DELIVERY: Reducing Maternal and Fetal Mortality** which contains information associated with the device lines as follows: IUP-400; IUP-450; IUP-500; IUP-550; IUP-600; IUP-650; IUP-700; IUP-750; Vacuum-assisted deliver (disposable silicone bell-shaped cups; manual vacuum pumps; reusable silicone bell-shaped cups; disposable polyethylene bell-shaped cups; disposable mushroom-shaped cups); Cordguard; Arom-Cot; Muc-X; Fetal Monitoring Supplies (fluid-filled IUPC; toco belts; fetal scalp electrodes; and fetal monitoring chart paper.

Exhibit L12: Representative promotional materials were obtained during the current inspection and a summary is as follows: **NEONATAL AND PEDIATRIC INTENSIVE CARE** which contains information associated with the device lines as follows: Umbili-Cath (complete umbilical catheter family); Picc-Nate (peripherally inserted central catheter); catheterization tray (general procedure tray); nutri-cath (silicone long-term enteral feeding catheter); hemo-nate (18 micron filtration system); disposa-hood (disposable infant respiratory hood); Uri-Cath (closed urinary drainage system for the neonatal/pediatric patient); Dialy-Nate (neonatal/pediatric disposable peritoneal dialysis set); Pala-Nate (silicone orotracheal protection device for neonates); Myelo-Nate (neonatal/pediatric CSF sampling set); Thora-Cath (silicon chest drainage catheter); and Deltran-Plus (closed needleless arterial blood collection system).

Exhibit L13: Representative promotional materials were obtained during the current inspection and a summary is as follows: **DELTRAN** which contains information associated with the device lines as follows: Deltran IV (complete

pressure transducer system); Deltran I (pressure transducer); Accessories and Kits (Delta-Flow – waveform accuracy; The Organizer; monitoring kits; Delta-Cal system verification); and Deltran-Plus (needleless arterial blood collection system).

Exhibit L14: Representative promotional materials were obtained during the current inspection and a summary is as follows: **GYNECOLOGY PRODUCTS CATALOGUE** which contains information associated with the device lines as follows: gynecology electrodes (letz/UtahLoop and conization); specialty electrodes (optimicro needle; epitome scalpel; and external lesion); electrosurgical generators (Finesse and Finesse II); smoke evacuation (Filtresse and smoke evacuation wand); filtration kits; electrosurgery accessories (filter pack; footswitches; internal filters; dispersive pads; electrosurgery pens; and fuses); ES/GYN instruments (lateral vaginal retractor; speculum; tenaculum; forceps; and specula – Graves; Collin; Pederson; Weisman-Graves; and disposable); endometrium assessment; and other gynecology products.

Exhibit L15: Representative promotional materials were obtained during the current inspection and a summary is as follows: **ELECTROSURGERY PRODUCTS CATALOGUE** which contains information associated with the device lines as follows: gynecology electrodes (Safe-T-Gauge and Tungsten Wire); C-Letz Conization electrode; Letz electrodes; specialty electrodes (Utah Optimicro Needle; External Lesion; and Epitome); electrosurgical generators (Finesse and Finesse II); smoke evacuation (Filtresse; smoke evacuation wand; and smoke evacuation filters); electrosurgery accessories (filters; internal filters; dispersive pads; footswitches; fuses; and electrosurgery pens); Electrosurgical instruments (Graves speculum; Collin speculum; Schroeder tenaculum; Pederson speculum; disposable speculum; Kogan Endocervical speculum; Graves Wide view speculum; Weisman-Graves speculum; lateral vaginal retractor); and Four-Way Vaginal Expanders.

Exhibit L16: Procedure entitled "LOT NUMBER FORMAT", Revision ~~/~~ dated ~~———~~ which defines the format to be utilized in the Lot Number System at the firm.

Exhibit L17: "MOLDING SET-UP SHEET" for machine number ~~———~~ ~~———~~ SETUP SHEET ~~———~~ Rev. ~~———~~ This is a representative example of an injection molding operational set-up sheet which includes processing equipment parameters.

Exhibit L18: FORM SPECIFICATION number [redacted] RUN SHEET-MOLDING; Revision [redacted], dated [redacted] The "RUN SHEET" (Page [redacted] documents the processing information (but not limited to) as follows:

Exhibit L19: TRAINING DOCUMENT number [redacted] entitled "INJECTION MOLDING PROCESS SET-UP AND PRODUCING PART", Revision [redacted] dated [redacted] Contains injection molding process set-up instructions (Page [redacted]; producing parts (Page [redacted]; and completing injection molding work orders (Page [redacted] Section [redacted] tates to [redacted] Section [redacted] states [redacted]

Exhibit L20: "Control Chart for Variables" for Part number [redacted], Revision, [redacted] Contains control limits for Mean and Range (LCL and UCL). Additionally, a sampling plan is specified for a sampling interval of [redacted] and a sample size of [redacted]

Exhibit L21: "Attribute Inspection Form" for Part number [redacted], Revision [redacted]. Contains visual inspection defect descriptions for flash, incorrect luer taper, short shot, and others. Additionally, a sampling plan is specified for a sampling interval of [redacted] and a sample size [redacted]).

Exhibit L22: Work order number [redacted] During this inspection, physical sample testing [redacted]) was observed in which the [redacted] was tested via use of a [redacted] These measurements are recorded on the "Control Chart for Variables" for Part number [redacted]

Exhibit L23: WORK ORDER [redacted], including WORK ORDER TRAVELER (Pages [redacted]; RUN SHEET (Page [redacted]; MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page [redacted] and Control Chart for Variables and Attribute Inspection Forms for processing which occurred between [redacted] (Pages [redacted]

Exhibit L24: WORK ORDER [redacted] including WORK ORDER TRAVELER (pages [redacted] RUN SHEET (Page [redacted]; MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page [redacted] MOLDING SET-UP SHEET (established set-up specifications) – Page [redacted] and Control Chart for Variables and Attribute Inspection Forms for processing which occurred [redacted]

Exhibit L24a: [redacted] dated [redacted] which addresses the description of change as [redacted] There is no reference to the UCL SPC limit being exceeded and there is no documented approval of these parts of being acceptable to have been processed above the established UCL.

Exhibit L25: WORK ORDER [redacted] including WORK ORDER TRAVELER (copy unreadable except for part label and total quantity; best possible copy obtained) – Pages [redacted] RUN SHEET (Page [redacted]; MOLDING PARAMETER CHART (actual equipment processing parameters under which the parts were manufactured) – Page [redacted] MOLDING SET-UP SHEET (established set-up specifications) – Page [redacted]; Control Chart for Variables and Attribute Inspection Forms for processing which occurred [redacted] [redacted] IN-PROCESS MOLD MAINTENANCE (Pages [redacted]

Exhibit L27: Several pages from an instruction manual for the [redacted]

Exhibit L28: Utah Medical Molding Machines, Materials, Equipment, Information Sheet dated [redacted] which includes a listing of the [redacted] molding machines which are present at the firm (Pages [redacted] A listing of injection molded parts (via part numbers); a description of the part; the mold number; and the machine(s) on which the part is manufactured (Page [redacted]

Exhibit L29: In-house molded parts dated [redacted] via part number and part description (Pages [redacted] Indented Bill of Material for [redacted] (Page [redacted]) and [redacted] (Page [redacted] devices dated [redacted] part number and description.

Exhibit L30: MANUFACTURING PROCEDURE number [redacted] entitled "MANUFACTURING LINE CLEARANCE"; Revision [redacted] dated [redacted]

Exhibit L31: QUALITY ASSURANCE PROCEDURE number [redacted] entitled "FIRST ARTICLE INSPECTION"; Revision [redacted] dated [redacted]

Exhibit L32: QUALITY ASSURANCE PROCEDURE number ——— entitled "INJECTION MOLDED PARTS"; Revision ———

Exhibit L33: TRAINING DOCUMENT number ——— entitled "MOLDING EQUIPMENT START-UP AND SHUT-DOWN PROCEDURES"; Revision —, dated ———

Exhibit L34: TRAINING DOCUMENT number ——— entitled "MOLDING MATERIAL HANDLING"; Revision — dated ———

Exhibit L35: TRAINING DOCUMENT number ——— entitled "REGRIND PROCEDURES"; Revision —, dated ———

Exhibit L36: TRAINING DOCUMENT number ——— entitled "INJECTION MOLD INSTALLATION AND REMOVAL"; Revision —, dated ———

Exhibit L37: TRAINING DOCUMENT number ——— entitled "MOLDING DEPARTMENT MOLDED PART HANDLING"; Revision —, dated ———

Exhibit L38: REQUEST FOR DEVIATION/WAIVER dated ———, number ——— for ——— his part is manufactured into the ——— device line.

Exhibit L39: REQUEST FOR DEVIATION/WAIVER dated ———; number ——— This part is manufactured into the ——— device line.

Exhibit L40: REQUEST FOR DEVIATION/WAIVER dated ———; number ——— This part is manufactured into the ——— device line.

Exhibit L41: RETURN GOODS AUTHORIZATION number ——— (NCMR number ———) dated ———. Part number ——— "failed testing" and was scrapped. This part is manufactured into the ——— device line. No

investigation upon the "failed testing" was conducted prior to this lot of injection molded parts being scrapped.

Exhibit L42: Nonconforming Material Report number — dated — associated with

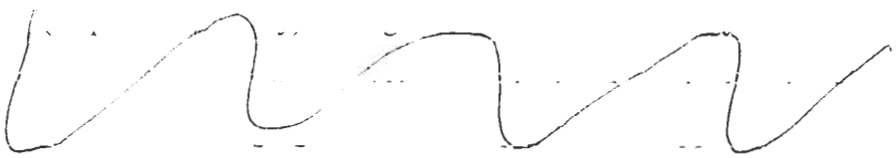


Exhibit L43: Nonconforming Material Report number — dated — associated with

Exhibit L44: Nonconforming Material Report number — dated — associated with

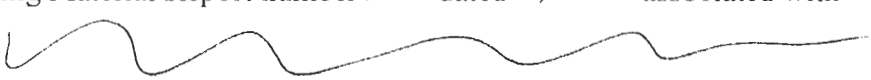


Exhibit L45: Material drying process includes a — dry time at a temperature of

The actual instructions, as found on the BOO, state

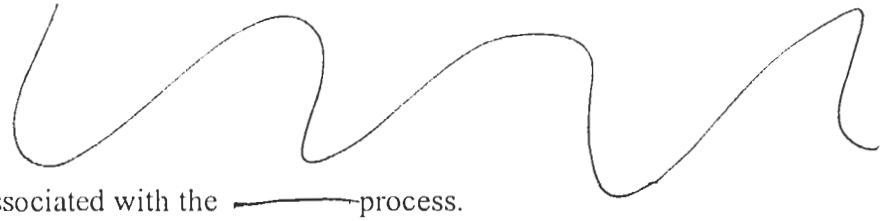
Exhibit L46: The material — specification sheet entitled — . Page states — Ben Shirley, Quality Manager, stated that the firm has not conducted a qualification upon this material and no additional drying information is contained within a design history file. This material specification sheet is the guide by which the firm processes the material utilized in the injection molding equipment.

Exhibit L47: A representative example of additional specification information associated with this material. Page — additionally states (Section — paragraph —

Exhibit L48: A representative example of the dehumidifying dryer — that the firm utilizes to dry the material which contains unit specification, preparation for operation, and maintenance and inspection

Exhibit L49: A TRAINING DOCUMENT entitled "MATERIAL DRYER CLEANING AND START UP", , Revision dated Page , Section states

Exhibit L50: A document entitled Final Design Review Minutes" dated This document addresses



associated with the process.

Exhibit L51: "TEST PROTOCOL QUALIFICATION, ", document number , Revision dated

Exhibit L52: "TEST REPORT, document number Revision , dated

Exhibit L53: Parts were injection molded for this protocol under "EXTRA PROCESS WORK ORDER (EPWO)" for Mr. Shirley stated that these parts were molded for I stated that these parts were molded prior to the approval of the "TEST PROTOCOL ", document number , Revision dated

Exhibit L54: Page is the Bill of Materials - BOM (Procedure: ; dated for part number Pages is the Bill of Operations – BOO (Procedure: ; dated for part number Mr. Shirley stated that this is the BOM and BOO associated with the processing of the above mentioned parts in association with "TEST PROTOCOL , document number , Revision dated There is no documentation or data to support that the process was conducted per The test report states that the There were processing parameters and it is not specified the number of parts that were processed under each parameter nor the number of parts which were

tested for cracks before and after the process.

Exhibit L55: PROCESS/RETORT NUMBER dated : A SUBMISSION FORM (Process/Retort number dated) which specifies that "Engineering Test Box for is to be sterilized. Ben Shirley, Quality Manager, stated that this "test box" contains the injected molded parts which are part of the , document number , Revision dated I stated that there is no clear delineation between the injection molded parts which are contained within this study and these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L56: The FINAL TEST REPORT: STERILITY TEST; LABORATORY NO. Page indicates that this laboratory number (identifies the sample taken from process number This documents the sterility of this batch of parts.

Exhibit L57:) PROCESS/RETORT NUMBEI dated : A SUBMISSION FORM (Process/Retort number , dated) which specifies that "Engineering Test Box for is to be sterilized. Ben Shirley, Quality Manager, again stated that this "test box" contains the injected molded parts which are part of the document number , Revision dated I stated that there is no clear delineation between the injection molded parts which are contained within this study and these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L58: The FINAL TEST REPORT: STERILITY TEST; LABORATORY NO. . Page indicates that this laboratory number)identifies the sample taken from process number This documents the sterility of this batch of parts.

Exhibit L59: PROCESS/RETORT NUMBER dated A SUBMISSION FORM (Process/Retort number dated which specifies that "Engineering Test Box for " is to be sterilized. Ben Shirley, Quality Manager, stated that this "test box" contains the injected molded parts which are part of the , document number , Revision dated I stated that there is no clear delineation between the injection molded parts which are contained within this study and

these parts which are being sterilized. Mr. Shirley agreed.

Exhibit L60: The [redacted] FINAL TEST REPORT: [redacted] STERILITY TEST; LABORATORY NO. [redacted] Page [redacted] indicates that this laboratory number [redacted] identifies the sample taken from process number [redacted]. This documents the sterility of this batch of parts.

Exhibit L61: A TRAINING DOCUMENT procedure entitled "ENVIRONMENTAL AND ACCELERATED AGING TEST"; procedure number [redacted] Revision [redacted] dated [redacted] Page [redacted] Section [redacted] states that [redacted]

Exhibit L62: Mr. Shirley provided when he was asked to provide documentation that the environmental cycle was conducted in accordance with the test protocol. This exhibit is a page from the "Environmental Cycle Log" and the entry that Mr. Shirley identified as the one associated with this experimental test is dated [redacted]. The product is identified as [redacted] and the estimated date out is documented as [redacted] I stated that [redacted] is a total of [redacted] exposure to the environmental chamber and the protocol (Exhibit L51, Page [redacted], Section [redacted] indicates that the cycle is approved for [redacted]" Therefore, this environmental cycle was not conducted in accordance with the established protocol.

Exhibit L63: Manufacturing procedure [redacted] entitled "HEAT ANNEALING PROCEDURE", Rev. [redacted], dated [redacted] Section [redacted], Page [redacted] states to [redacted] (section [redacted]. The annealing process qualification associated with injection molded part [redacted]) is not complete in that data/documentation does not exist associated with the qualification/validation study associated with the annealing oven.

Exhibit L64: The current annealing procedure which is currently being utilized during [redacted]. Manufacturing procedure [redacted] entitled "HEAT ANNEALING PROCEDURE", Rev. [redacted] dated [redacted] The annealing oven operational parameters are the same as mentioned above and found within the procedure within section [redacted] Page [redacted]

Exhibit L65: Promotional material page from an industrial bench oven catalog entitled "THE GRIEVE CORPORATION INDUSTRIAL AND LABORATORY OVENS AND FURNACES" which provides a description for the [redacted] oven which is currently being utilized by the firm to anneal injection molded parts. Mr. Shirley provided this information and indicated that it is associated with the annealing oven which is currently being utilized by the firm.

Exhibit L66: Drawing/Number [redacted], Rev. [redacted], dated [redacted] entitled [redacted] drawing and part specifications (dimensions).

Exhibit L67: Bill of Materials; Procedure number [redacted], dated [redacted] for [redacted]. Part number; revision, quantity, references, ECO No. which specifies the material needed to manufacture this part.

Exhibit L68-L79: "Certificate of Calibration" from [redacted], Instrument Data Report; and Preventive Maintenance documents. A representative example of injection molding equipment "Certificates of Calibration" and Preventive Maintenance on machine numbers as follows: [redacted]

Exhibit L80: NCMR number [redacted] dated [redacted], which states that the description is [redacted]" A hand written statement (dated [redacted] indicates that [redacted] There is no scientific documentation or data to support this decision to use as is.

Exhibit L81: A "REQUEST FOR DEVIATION/WAIVER", document number [redacted] dated [redacted]. The lot numbers associated with this document are [redacted]: The description of the deviation/waiver (block [redacted] is stated as [redacted]" There is no scientific documentation or data to support this decision to use as is.

Exhibit L82: Revision entitled "STATISTICAL PROCESS CONTROL CHART PROCEDURE FOR MOLDING" dated Section (Page states to Page , Section any point is

Exhibit L83: Revision (the previous version) of Exhibit L82 dated and is included within this report as reference.

Exhibit L84: A "CHANGE PROPOSAL" number dated which the description of change is to The reason for the change states At the beginning of this inspection, the had not per this Change Proposal. Release dated changed

Exhibit L85: CHANGE PROPOSAL number corrected version on document; revision was not changed when the document was; Release dated

Exhibit L86: Data utilized by the firm to ; calculated using data from work orders as follows: Work order numbers found on top of sheet;

Exhibit L87: "Steps for Constructing X Bar – R Charts" which contains the formula for calculate (according to Ben Shirley);

Exhibit L88: CHANGE PROPOSAL number initial release of Release date dated

Exhibit L89: The firm's current Software Validation Plan dated

Exhibit L90: The ' dated

Exhibit L91: Drawing entitled drawing number dated

Exhibit L92: MOLDING SET-UP SHEET —Document Number—; Revision —; for Part Number —

Exhibit L93: BOO (Bill of Operation); Process number —; dated — (the date of printing). Mr. Shirley stated that this has —

Exhibit L94: QUALITY ASSURANCE PROCEDURE number — entitled "MOLDING AND EXTRUSION INSPECTION PROCEDURE"; Revision—, dated —

Exhibit L95: QUALITY ASSURANCE PROCEDURE number — entitled —; Revision —, dated —

Exhibit L96: "TEST PROTOCOL" number —, Revision— dated — entitled "SWITCHING STATUS CODES" which describes the test procedure for qualifying Inspection Switching Status Inquiry and the switching status subroutine of Direct Results.

Exhibit L97: "TEST REPORT" number —; Revision—, dated — entitled "VALIDATION OF SWITCHING STATUS CODES" which states that the raw data is attached to —The conclusion of this test report states that —

Exhibit L98: "CHANGE PROPOSAL" number —; dated —

Exhibit L99: "CHANGE PROPOSAL" number —, dated : —

Exhibit L100-L112: — which were changed within CP —

Exhibit L113: "TEST PROTOCOL" number —, Revision —; dated — entitled — " which describes the qualification process

Exhibit L114: "TEST REPORT" number [redacted] Revision [redacted] dated [redacted] entitled [redacted] The conclusion of this test report states that [redacted]

Exhibit L115: "SOFTWARE SPECIFICATION" number [redacted] Revision [redacted] dated [redacted] which describes the specifications of the software used for the purpose of operating the [redacted]

Exhibit L116: "TEST PROTOCOL" entitled [redacted], number [redacted], Revision [redacted], dated [redacted] which describes the qualification of the final tester for [redacted]. This qualification addressed the issues as follows: [redacted]

Exhibit L117: "TRAINING DOCUMENT" number [redacted], Revision [redacted], dated [redacted] entitled "PERMANENT EQUIPMENT ASSEMBLY AND SERVICICNG GUIDELINES".

Exhibit L118: Current revision of Exhibit L117 (Revision [redacted]) dated [redacted] and is attached for reference. Section [redacted] Page [redacted] has been [redacted] No deficiencies were noted.

Exhibit L119: [redacted] OPERATOR'S MANUAL [redacted]. Page [redacted] Section [redacted]

Exhibit L120: "CHANGE PROPOSAL" number [redacted] dated [redacted] in which the description of the change is to change [redacted]

[redacted]. The CP [redacted] The reason for change states that [redacted]

Exhibit L121: A preventive maintenance (PM) work order for static control mats (dated [redacted]. This document indicates that static control mats have [redacted] PM performed on them. Mr. Shirley stated that according to this PM indicates that all mats are to be tested [redacted] therefore, there is no need for the firm to specify which ESD mats should be tested.

Exhibit L122: The "Daily Cleaning log for Production areas, Manufacturing [redacted]' (Form [redacted] Rev. [redacted]) which document these [redacted] cleaning activities between [redacted].

Exhibit L123: QUALITY ASSURANCE PROCEDURE number [redacted]; Revision [redacted]; dated [redacted]; entitled "INTERNAL AUDIT PROCEDURE".

Exhibit L124: FORM SPECIFICATION number [redacted]; Revision [redacted], dated [redacted], entitled "INTERNAL AUDIT SCHEDULES".

Exhibit L125: FORM SPECIFICATION number [redacted]; Revision [redacted]; dated [redacted] entitled "INTERNAL AUDIT MRB REVIEW RECORD".

Exhibit L126: FORM SPECIFICATION number [redacted]; Revision [redacted], dated [redacted] entitled "INTERNAL AUDIT CORRECTIVE ACTION RECORD".

Exhibit L127: FORM SPECIFICATION number [redacted]; Revision [redacted], dated [redacted] entitled "INTERNAL AUDIT PLAN AND AUDIT REPORT FORM".

Exhibit L128: INTERNAL AUDIT PLAN assigned audit of "Corrective & Preventive Action"; Page [redacted] addresses numerous quality records reviewed including CARs (corrective action requests/reports).

INVESTIGATOR MONICA J. WILKINS EXHIBITS:

M1: Software Validation Plan, Date ; Software Development, Validation and Documentation, Document No. , Revision , Date , Software Validation Plan Schedule

M2: Validation Test Protocol, Document No. Revision Draft

M3: Memorandum 2003 FDA-483 Response File, Date 02/13/04 and Software Validation Plan, Date

M4: Complaint Numbe

M5: r MRB Review,

M6: Utah Medical Product, Inc. – CAPA CAR Log

M7: Deviation/Waiver Log , and Deviation/Waiver Log

M8: Utah Medical Product NCMR Log, dates

M9: Corrective and Preventive Action (CAPA) procedure, Document No. , Revision Revision Date

M10: Review of Utah Medical Quality System,

M11: MRB Review on

M12: MRB Review on

M13: Custom Failure Codes

M14: Complaint Number

M15: Complaint Number

M16: Complaint Number

M17: Complaint Number

M18: Complaint Number

M19: Complaint Number

M20: Complaint Number

M21: Complaint Number

M22: Complaint Number

M23: Complaint Number

M24: Complaint Number

M25: Complaint Number

M26: Customer Complaint System, Document No. , Revisio ; Revision Date

M27: Customer Complaint Investigation, Document No. , Revision Revision Date

M28: Post Distribution Monitoring, Document No. Revision Revision Date

M29: Corrective Action, CA No. Originator Date

M30: Summary of Complaint Evaluations, from date [redacted]

M31: Complaint Number [redacted], Received Date [redacted]

M32: [redacted] Comparative Resistance Study Map

M33: [redacted], Comparative Resistance Study, Protocol No. [redacted], Issue Date [redacted]

M34: [redacted], Final Report [redacted], Comparative Resistance Study, Laboratory No [redacted], Report Date [redacted]

M35: [redacted] Comparative Resistance Study, Protocol No. [redacted] Issue Date [redacted]

M36: [redacted], Final Report [redacted] Comparative Resistance Study, Laboratory No. [redacted] Report Date [redacted]

M37: [redacted], Comparative Resistance Study, Protocol No. [redacted], Issue Date [redacted]

M38: [redacted], Final Report [redacted] Comparative Resistance Study, Laboratory No. [redacted], Report Date [redacted]

M39: [redacted] Comparative Resistance Study, Protocol No. [redacted] Issue Date [redacted]

M40: [redacted] Comparative Resistance Study, Laboratory No. [redacted], Report Date [redacted]

M41: [redacted], Comparative Resistance Study, Protocol No. [redacted] Issue Date [redacted]

M42: [redacted], Final Report [redacted] Comparative Resistance Study, Laboratory No. [redacted] Report Date [redacted]

M43: [redacted] Comparative Resistance Study, Protocol No. [redacted], Issue Date [redacted]

M44: [redacted], Final Report Comparative Resistance Study, Laboratory No. [redacted], Report Date [redacted]

M45: Deltran Technology For Critical Care product brochure/catalog, Part Number [redacted] Revision Date [redacted]

M46: [redacted] Memorandum, Date [redacted] for the Comparative Resistance Studies

M47: [redacted] Master Record, Facility Description, [redacted] Date [redacted] Revision [redacted]

M48: [redacted] Validation, Protocol No. [redacted] Issue Date [redacted] Pages [redacted] Completed [redacted] Validation Test Protocol Final Report, Document No. [redacted], Revision [redacted], Date [redacted] for validation completed on [redacted] Pages [redacted] Final Report [redacted] Comparative Resistance Study, Laboratory No. [redacted] Report Date [redacted] Pages [redacted]

M49: Test Protocol [redacted] Test Protocol, Document No. [redacted]

Revision Date , Pages , and, Completed Validation Test Protocol Results, Document No. , Approval Date , Pages

M50: Few documents obtained from the and Completion Approval Date (refer to Exhibit #49)

M51: Test Protocol, Document No. , Revision Date

M52: Product Density Test Protocol, Document No. , Revision , Revision Date

M53: Product Density Test Report, Document No. , Revision Revision Date

M54: Test Protocol, Document No. , Revision Revision Date

M55: Test Report, Document No. Revision Revision Date

M56: est Protocol, Document No. Revision , Revision Date

M57: Test Report, Document No. , Revision , Revision Date and a few documents obtained from the validation binders containing the data

M58: Revalidation Test Protocol, Document No. Revision Revision Date

M59: Revalidation Test Report, Document No. , Revision , and a few documents obtained from the validation binders containing the data

M60: Utah Medical Products Revalidation Assessment for Protocol No. , Date Approval Date and a few documents obtained from the validation binders containing the data

M61: Revalidation Assessment Test Protocol, Document No. Revision Revision Date

M62: Revalidation Assessment Test Report , Document No. , Revision , Revision Date and a few documents obtained from the validation binders containing the data

M63: Revalidation Assessment , Test Report, Document No. , Revision Approval Date , and a few documents obtained from the validation binders containing the data

M64: Comparative Resistance Study, Protocol No.

M65: Comparative Resistance Study, Laboratory No Report Date

M66: Change Proposal (CP) , Date

M67: Sterilization Load Preparation procedure, Document No. Revision Revision

M68: Sterilization Cycle Process/Retort , Date

M69: Memorandum 2003 FDA-483 Response File, Date 02/13/04, Subject: Observation 1C

M70: Real Time Packaging Integrity Test Protocol, Document No. Revision Revision Date

M71: Real Time Packaging Integrity Test Protocol, Document No. , Revision Revision Date

M72: Utah Medical Products, Inc. Quality Manual, Revision , Revision Date

M73: Manufacturing Process Qualification and Validation, Document No. Revision Revision Date

M74: Sterile Packaging Design, Document No. Revision , Revision Date

M75: Real Time Packaging Integrity Test Report, Document No. , Revision , Revision Date

M76: Change Proposal (CP) No. , Date , which includes the data for Test Report No.

M77: Pouch or Tray Seal Testing, Document No. Revision Revision Date

M78: Qualification Test Protocol, Document No. , Revision Revision Date

M79: Environmental and Accelerated Aging Tests procedure, Document No. , Revision Revision Date

M80: Qualification Test Report, Document No. Revision , Revision Date

M81: Extra Process Work Order (EPWO) Lot No. Date

M82: System Design Specification, Document No. Revision Revision Date

M83: Qualification of Test Report, Document No. Revision , Revision Date

M84: Qualification of Intran Plus For A Second ETO Cycle Test Report, Document No. Revision , Revision Date

M85: procedure, Document No. Revision , Revision Date

M86: Qualification of the Test Report, Document No. Revision Revision Date

M87: Extra Process Work Order (EPWO), , Date

M88: Change Proposal (CP) Date

M89: Master Record (DMR), Document No. Revision , Revision Date

M90: [redacted] Residuals Testing Test Protocol, Document No. [redacted], Revisior [redacted] Revision Date [redacted]

M91: [redacted] Residual Test Results Test Report, Document No. [redacted] Revision [redacted] Revision Date [redacted]

M92: Final Report Sterilant [redacted] Laboratory No. [redacted] Report Date [redacted]

M93: [redacted] Test Results Test Report, Document No. [redacted], Revision [redacted], Revision Date [redacted]

M94: Document Distribution System Test Protocol, Document No. [redacted] Revision [redacted] Revision Date [redacted]

M95: Document Distribution System Software Definition, Document No. [redacted] Revision [redacted] Revision Date [redacted]

M96: Document Distribution System Validation Test Report, Document No. [redacted] Revision [redacted] Revision Date [redacted]

M97: Memorandum, dated [redacted] Subject: Observation 4 and Risk Management/Risk Assessment Plan, [redacted] Intran Catheter Brittleness

M98: UTMD MDR Reports – listing (Page [redacted] and MedWatch reports received by UTMD (Page [redacted]

M99: Memorandum, dated [redacted], Subject: Observation 6

M100: Microbial Bioburden Testing of Devices procedure, Document No. [redacted] Revisior [redacted] Revision Date [redacted]

M101: Environmental Control and Monitoring procedure, Document No. [redacted], Revision [redacted] Revision Date [redacted]

M102: Chapter 3. Aerobic Plate Count, FDA Bacteriological Analytical Manual, 8th Edition (Revision A)/1998

M103: Microbial Bioburden Testing of Devices, Document No. [redacted] Revision [redacted], Revision Date [redacted]

M104: [redacted] Bioburden Testing Technique Form, [redacted]

M105: [redacted] Bioburden Testing Technique Form, [redacted]

M106: [redacted] Bioburden Testing Technique Form, [redacted]

M107: Bioburden procedure, [redacted], SOP Executive Summary, Change Control Number [redacted] Document No. [redacted], Date [redacted]

M108: IUP Functionality Test Protocol, Document No. [redacted], Revision [redacted] Revision Date [redacted]

M109: 2003 FDA-483 Response File Memorandum, date 02/17/04, Addendum, RE: Item 11

M110: 2003 FDA-483 Response File Memorandum, date 02/13/04, Addendum, RE: Item 12

M111: 2003 FDA-483 Response File Memorandum, date 02/13/04, Addendum, RE: Item 13

M112: IUP Functionality Test Protocol, Document No. [redacted] Revision [redacted] Revision Date [redacted]

M113: Qualification of a [redacted] Test Protocol, Document No [redacted]

Revision Revision Date

M114: Qualification of a Test Report, Document No. Revision Revision Date

M115: Design History File, Directive for the Development of Products, Product Name – Part Number , Date and examples of data

M116: Testing procedure, Document No. , Revision Revision Date

M117: Final Report After Accelerated Aging, Laboratory No Report Date

M118: Final Report After Accelerated Aging, Laboratory No. Report Date

M119: Final Report Comparative Resistance Study, Laboratory No. Report Date

M120: 2003 FDA-483 Response File Memorandum, date 02/13/04, Addendum, RE: Item 14

M121: Preventive Maintenance Packaging Machine, Work Order Completion Date

M122: Preventive Maintenance Packaging Machine, Work Order , Completion Date

M123: 2003 FDA-483 Response File Memorandum, date 02/17/04, Addendum, RE: Item 16

M124: Management Review of Quality System procedure, Document No. Revision , Revision Date

M125: Risk Management procedure, Document No. Revision Revision Date

M126: Risk Analysis procedure, Document No. , Revision , Revision Date

M127: Risk Assessment procedure, Document No. , Revision , Revision

M128: Sterilization procedure, Document No. Revision , Revision Date

M129: Sterile Packaging Design procedure, Document No. Revision Revision Date

M130: Process Challenge Device (PCD) procedure, Document No. , Revision Date

M131: ETO Sterilization Process procedure, Document No. , Revision , Revision Date

M132: Final Product and Subassembly Release procedure, Document No. Revision Revision Date

INVESTIGATOR RALPH W. JERNDAL EXHIBITS:

Exhibit R1: A list of the parts produced by extrusion molding at this facility, the highest volume part produced is the Part

Exhibit R2: Part , Tubing, UMP Extruded catheter body component), parts, work order , start date

Exhibit R3: Part Tubing, UMP Extruded, parts, work order , start

Exhibit R4: Part Tubing, Dual Lumen (catheter body component for Fluid-Filled IUP device), units, work order # start date

Exhibit R5: Part # Part #, Introducer Polypropylene, units, work order start date

Exhibit R6: Change Proposal (CP) submitted introduced This CP affected the majority of procedures previously in place, directing the extrusion process. Page lists the documents affected and their revision changes. The CP attaches copies of the previous, and the new, revisions of the majority of the listed documents.

Exhibit R7: Manufacturing Procedure Revision, dated "Manufacturing Line Clearance" - this document directs the clearing of a workstation or production line of materials, components, labels, and documents to ensure there is no cross-contamination between difference work orders.

Exhibit R8: Manufacturing Procedure 'Extruder Equipment Setup" – this document describes the procedure for the extruder equipment setup including reference to part specific setup sheets for processing parameters to be used.

Exhibit R9: Form Specification Extruder Run Sheet" – extruder run sheet for recording selected processing parameters.

Exhibit R10: "Work-Order Bill" – describes the process in which a work order is picked by staging and built by manufacturing using the System.

Exhibit R11: [redacted], Revision [redacted], dated [redacted] "Molding Material Handling" – this document provides an outline for material handling, including component mixing, i.e. resin and color concentrate.

Exhibit R12: [redacted], Revision [redacted], dated [redacted] "Material Dryer Cleaning & Startup" – this document describes the procedure for the resin dryer cleaning and startup and cites the BOO as documenting the minimum time and temperature specification. It also directs recording of this information on the BOO for each batch.

Exhibit R13: [redacted] Revision [redacted], dated [redacted] "Extruder String-up & Production" – this procedure directs additional requirements for extruder setup and extrusion molding production. This procedure directs introduction of material to be extruded and establishing procedures to achieve process stabilization.

Exhibit R14: [redacted], Revision [redacted], dated [redacted] directs the setup of the catheter body printing. It is performed in conjunction with the catheter extrusion process.

Exhibit R15: [redacted], Revision [redacted], dated [redacted] – describes the procedure for printing labels for extrusion product batching boxes.

Exhibit R16: [redacted] Revision [redacted], dated [redacted] Label Reconciliation and Verification" – instructions for reconciling and verifying labels printed for production.

Exhibit R17: Form [redacted], Revision [redacted] " (Each of the other [redacted] parts produced by extrusion molding has its own assigned attribute inspection form.).

Exhibit R18: [redacted], Revision [redacted], dated [redacted] Statistical Process Control Chart Procedure For Molding" – this is a generic procedure defining this firm's statistical process control (so-called) practices for molding both injection and extrusion.

Exhibit R19: [redacted], Revision [redacted], dated [redacted] this document describes the inspection procedures and criteria to be used in the acceptance of the extruded dual lumen product.

Exhibit R20: Drawing —, Revision — dated — - this is an example of an extruded part drawing, in this case, the part — Mr. Shirley supplied this drawing with the indicated hand-drawn lines illustrating the particular dimensions that are checked with the indicated instrument as listed on the drawing.

Exhibit R21: — , Revision —, dated — "Extruder Equipment Cleaning and Shut Down" – this document describes the procedure for shutting down, purging and cleaning the extruder following a production batch run.

Exhibit R22: — Revision — date — - this general procedure defines criteria for final product and subassembly inspection and release, including release of sterile products to sterilization by Quality Assurance, release of sterile final product for distribution, and — Table of Inspection Criteria and Method of Inspection concerning review of work order device history record packets review.

Exhibit R23: Extruder setup sheet —, Revision — established under Change Proposal (CP) —, dated —.

Exhibit R24: An older extruder setup sheet start dated — for part — — work order: —

Exhibit R25: Engineering Drawing —, Revision — dated —

Exhibit R26: Engineering Drawing — revision —, dated —

Exhibit R27: Part — Bill of Operations (BOO), the currently applicable Revision — dated —

Exhibit R28: Part — BOO, Revision — dated —

Exhibit R29: Material Specification —, Revision — dated —

Exhibit R30: Material Specification — Revision — dated —

Exhibit R31: [redacted], Revision [redacted] Extruder Setup Sheet, established as a formerly controlled document under Change Proposal [redacted] dated [redacted]

Exhibit R32: Engineering Drawing [redacted] Revision [redacted] dated [redacted]

Exhibit R33: Material Specification [redacted], Revision [redacted], dated [redacted]

Exhibit R34: Material Specification [redacted] Revision [redacted] dated [redacted]

Exhibit R35: Change Proposal [redacted], date submitted, [redacted], date released, [redacted] This change proposal introduced changes to the [redacted]

Exhibit R36: Extruder Setup Sheet, [redacted], Revision [redacted], Part [redacted] (for the INTRAN Plus IUP device).

Exhibit R37: Extruder Setup Sheet [redacted], Revision [redacted], the [redacted]

Exhibit R38: List of work orders completed since [redacted] up through [redacted], for the INTRAN Plus IUP Device Final Assembly.

Exhibit R39: Manufacturing Procedure [redacted], Revision [redacted], dated [redacted]

Exhibit R40: Manufacturing Procedure [redacted] Revision [redacted] dated [redacted]

Exhibit R41: Manufacturing Procedure [redacted], Revision [redacted] dated [redacted]

Exhibit R42: Work Order [redacted] Assembly [redacted] start date

Exhibit R43: Work Order [redacted] start date [redacted]

Exhibit R44: Work Order [redacted], start date [redacted]

Exhibit R45: Test protocol [redacted] Revision [redacted] dated [redacted]

Exhibit R46: Test report [redacted], Revision [redacted], dated [redacted]

Exhibit R47: Memo dated [redacted], subject: [redacted] that describes title and contents of a variety of Legacy documents, miscellaneous materials, related to extrusion molding and its equipment and its storage locations.

Exhibit R48: Engineering Change Request C/R [redacted], date implemented [redacted] this documentation contains qualification work done of [redacted]

Exhibit R49: Engineering Change Request C/R [redacted], date implemented [redacted] this document introduces dimensional changes to the [redacted] part number for extrusion tubing, [redacted]

Exhibit R50: Engineering Change Request C/R [redacted], date implemented [redacted] updates the build of materials and Bill of Operations with the [redacted] and its [redacted] that is to replace the [redacted] in the Part [redacted]

Exhibit R51: On Wednesday, 2/04, I reviewed CAR [redacted] originator/date [redacted] This is the Corrective Action document presented for review at this time.

Exhibit R52: Complaint [redacted]

Exhibit R53: On Saturday, 2/07, Ben Shirley supplied an updated version of Corrective Action . This is the Corrective Action document presented for review at this time.

Exhibit R54: Material Specification , Revision , dated

Exhibit R55: Manufacturing Procedure , Revision dated Pressure Tubing Assembly,

Exhibit R56: Manufacturing Procedure , Revision dated

Exhibit R57: Test Report , Revision , dated

Exhibit R58: Test Protocol , Revision , dated "Female Luer Connector Qualification, P/N ; This Test Protocol states,

Exhibit R59: Engineering drawing revision dated

Exhibit R60: Manufacturing Procedure Revision , dated

This procedure directs this peration.

Exhibit R61: Engineering Change Request , dated involves the change from for the used in this operation with a reason given as, ." Attached is the procedure Revision Change from

Exhibit R62: Bill of Materials for the lated

Exhibit R63: , Revision dated , This is the final electrical testing and ' functional test for the

Exhibit R64: Manufacturing Procedure [redacted], Revision [redacted], dated [redacted]

Exhibit R65: Memo from [redacted], Dated [redacted] subject: [redacted]

Exhibit R66: Test Protocol [redacted] Revision [redacted] dated [redacted] (This protocol's reported purpose on page [redacted] states, [redacted]

Exhibit R67: "Master Test Plan for [redacted], dated [redacted]

Exhibit R68: Lab book test data, dated [redacted] (pull test data on page [redacted]

Exhibit R69: Test Protocol [redacted] revision [redacted], dated [redacted]

Exhibit R70: Corrective/Preventive Action Request CAR [redacted] originator date [redacted] copy supplied On Wednesday, 2/4/04.

Exhibit R71: Complaint [redacted]

Exhibit R72: Complaint [redacted]

Exhibit R73: Complaint [redacted]

Exhibit R74: Complaint [redacted]

Exhibit R75: CP [redacted] dated entered [redacted] This change involved updating the manufacturing procedure for this operation, [redacted] from Revision [redacted] to Revision [redacted] adding an improved drawing illustrating the bonding areas, and changing section [redacted] to read, [redacted], versus [redacted]' in the old revision.

Exhibit R76: Operator training record dated [redacted] corrective action for CAR [redacted]

Exhibit R77: CP [redacted] dated entered [redacted] notes as description of change: [redacted] And reason for the

change, [redacted]" The bonding procedure, [redacted] was revised to the new and current Revision [redacted] The detailed changes to the attached marked-up copy are found under Sections [redacted]

Exhibit R78: Employee training record dated [redacted] is attached, corrective action for CAR [redacted]

Exhibit R79: Current manufacturing procedure [redacted], revision [redacted] dated [redacted]

Exhibit R80: Test Report [redacted] Revision [redacted], dated [redacted]

Exhibit R81: Test Protocol [redacted], revision [redacted], dated [redacted]

Exhibit R82: Test Report [redacted] revision [redacted] dated [redacted]

Exhibit R83: List of [redacted] assemblies completed [redacted] 1 through [redacted]. subject of CAR [redacted], is apparently co-incident with the introduction of the new assembly.

Exhibit R84: Change Procedure, CP number [redacted], approval date [redacted] that introduces the new, [redacted] into the [redacted] production.

Exhibit R85: W/O [redacted]

Exhibit R86: W/O [redacted]

Exhibit R87: W/O [redacted]

Exhibit R88: W/O [redacted]

Exhibit R89: [redacted] references from the MRB meeting of [redacted] the only documentation in the MRB proceedings relating to CAR [redacted]

Exhibit R90: Update to CAR [redacted] This CAR page adds the additional affectivity verification, [redacted]

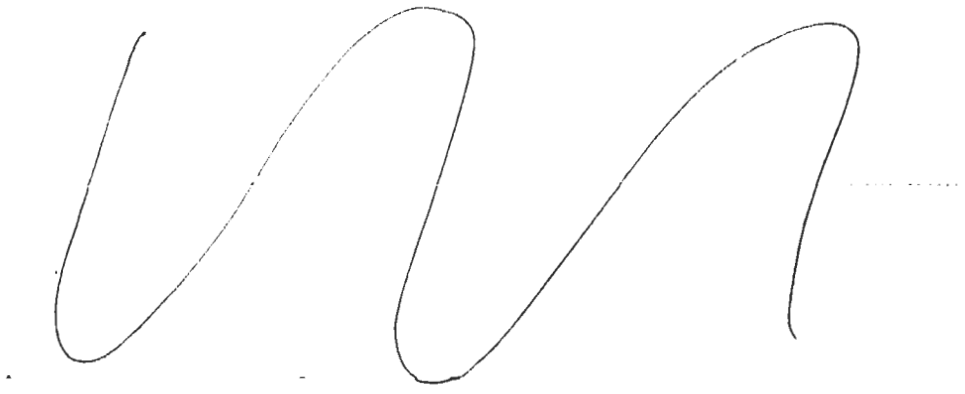


Exhibit R91: Label Specification — , revision — lated

Exhibit R92: revision

Exhibits R93 – R98 not used.

Exhibit R99: Bill of Operations (BOO) for Part
Revision — dated

No Look-back Documented

Complaint #	Date Received	Exhibit #
		R100
		R101
		none
		R102

Exhibit R102: Complaint , receipt date ; is attached as. Exhibit page — failure code cites, However, at the bottom of page it states, under results,

Complaint & Service Look-back Documented

Complaint #	Date Received	Exhibit #
[illegible]		none
		R105
		R106
		R107
		none
		R108
		none
		R109

Complaint History Look-back Only Documented

Complaint #	Date Received	Exhibit #
[illegible]		R110
		R111
		none
		R112
		none

Service History Look-back Only

Complaint #	Date Received	Exhibit #
[illegible]		R113
		R114
		R115
		R116

Exhibit R116: Complaint [illegible], receipt date [illegible] The failure code [illegible] is found on page [illegible] Under the heading, Investigation Findings, at the bottom of page [illegible], it states, "[illegible]"

Look-back Documented in Customer Letter Only

Complaint #	Date Received	Exhibit #
[illegible]		none
		none

Look-back Time Unspecified

Complaint #	Date Received	Exhibit #
[illegible]		none

Complaint & Service History Look-back for Unit Only Documented

Complaint #	Date Received	Exhibit #
[redacted]		R117
		R118
		none
		none

Exhibit R119: Risk Management plan, [redacted], with attached Risk Assessment Process for [redacted] Complaints, dated [redacted]

Exhibit R120: Most recent Certification of Calibration for the [redacted]

ATTACHMENTS

Written by Investigator Medina.

Attachment 1: FDA-482, Notice of Inspection, dated 2/2/04 issued to Kevin L. Cornwell, Chairman/CEO (1 page)

Attachment 2: FDA-483, Inspectional Observations, dated 3/3/04 issued to Kevin L. Cornwell, Chairman/CEO reviewed during the close-out meeting; signed and unannotated (7 pages)

Attachment 3: FDA-483, Inspectional Observations, dated 3/3/04 issued to Kevin L. Cornwell, Chairman/CEO reviewed during the close-out meeting; corrected, signed, and unannotated (7 pages)

Attachment L1: MDR text key number , for the Tender Touch Ultra Cup with a report date of 9/2/03.

Attachment L2: MDR text key number for the Umbilical Catheter with a report date of 8/27/03.

Attachment L3: MDR text key number for an Unknown UTMD loop electrode/electrosurgical electrode with a report date of 6/2/03 being utilized during a LEEP procedure in which the loop electrode melted.

Lori A. Medina, Investigator

Ralph W. Jerndal, Investigator

Monica J. Wilkins, Investigator