TABLE OF CONTENTS

SUMMARY 1
ADMINISTRATIVE DATA 3
HISTORY 4
INTERSTATE COMMERCE 5
JURISDICTION 5
RESPONSIBILITY 6
MANUFACTURING / DESIGN OPERATIONS 8
MANUFACTURING CODES 10
COMPLAINTS / PRODUCT DEFECTS 11
OBJECTIONABLE CONDITIONS 12
REFUSALS 87
GENERAL DISCUSSION WITH MANAGEMENT 87
INSPECTIONAL GUIDANCE 89
VOLUNTARY CORRECTIONS 100
EXHIBITS AND SAMPLES COLLECTED 101
ATTACHMENTS 109

SUMMARY

Written by CSO Chase-Off

This was a Level III, QSIT inspection conducted at the request of DEN-DO Compliance per FACTS Assignment 385085, Compliance Number 8580-0, and in accordance with C.P. 7382.845, Inspection of Medical Device Manufacturers. Utah Medical Products, Inc. (UTMD) manufactures various Class II devices for labor and delivery obstetrics, neonatal intensive care, blood pressure monitoring, gynecology, urology and electro surgery. Devices may or may not be sterilized. Further, UTMD distributes some vendor items.

UTMD has an extensive inspectional history including a 1995 inspection that was classified OAI and resulted in a Warning Letter. The firm was inspected in 1998; the inspection was classified NAI. The firm was again inspected 6/4/01-6/8/01. That inspection was OAI and resulted in a Warning Letter. A follow-up inspection to the Warning Letter was conducted 3/26/02-4/15/02. That inspection was classified OAI; however, no action has been taken regarding that inspection. A limited inspection was conducted 6/4/02-6/5/02 to collect a documentary sample in support of the 3/02 inspection.

On 2/24/03, credentials were presented to Mr. John R. Smith, Quality Manager, Mr. Ben Shirley, Vice President of Engineering and Mr. Kevin L. Cornwell, CEO and Chairman. The FDA-482 was

issued to Mr. Smith, Quality Manager and Management Representative. Ms. Karen A. Coleman, Investigator from the Division of Field Investigations participated in the inspection.

The current inspection included a review of molding, extrusion, electrical assembly and sterilization processes including validation. Injection molding, extrusion molding, electrosurgical unit assembly and troubleshooting, and IUP manufacturing process were observed in whole or part. Documents controlling the quality system and manufacturing procedures were reviewed.

On 3/12/03, a FDA-483, Inspectional Observations, was issued to Mr. Cornwell in the presence of Mr. Smith and Mr. Shirley.

The current inspection revealed new and continuing deviations from the CGMP/QSR. Objectionable conditions included: inadequate comparative resistance, bioburden and real time packaging integrity studies; lack of validation in sterilization, molding and gluing processes; lack of computer software validation; inadequate corrective and preventive action procedures; failure to take all actions necessary to prevent the reoccurrence of non-conforming product; failure to verify or validate corrective and preventive actions; failure to submit MDR reports; failure to control environmental conditions; failure to establish process controls; use of inspection equipment that is not suitable for its intended use; failure of the DHR to meet the requirements of the DMR; failure of procedures to ensure that design outputs meet design inputs; design validation did not ensure the device conforms to the user needs and intended uses; failure to establish procedures for validation or verification of a design change; design validation was not conducted under real or simulated use conditions; appropriate design or construction of equipment was not ensured; preventative maintenance schedules not established or implemented; incomplete documentation of equipment identification; lack of document review; and ineffective quality audits.

Mr. Cornwell promised correction of some, but not all items, as noted in the annotations of the FDA-483.

A documentary sample 199272 was collected to document interstate commerce and deviations from the QSR. The Affidavit associated with this sample was reviewed by Mr. Cornwell but was not signed.

Mr. Smith and Mr. Cornwell refused to allow some raw data to be photo copied during the inspection. Further, Mr. Cornwell would not provide the names of employees listed on the firm's organizational charts, and would not allow employees to be interviewed regarding their specific duties.

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

ADMINISTRATIVE DATA

Inspected firm: Utah Medical Products, Inc
Location: 7043 South 300 West
Midvale, UT 84047

Phone: (801) 566-1200
FAX: (801) 566-2062
Mailing address: 7043 South 300 West
Midvale, UT 84047

Dates of inspection: 2/24/2003, 2/25/2003, 2/26/2003, 2/27/2003, 2/28/2003, 3/3/2003, 3/4/2003, 3/5/2003, 3/6/2003, 3/12/2003
Days in the facility: 10
Participants: Ricki A. Chase-Off, Investigator
Karen A. Coleman, Investigator

Written by CSO Chase-Off

Utah Medical Products, Inc. (UTMD) routinely operates [illegible] Monday-Friday, [illegible] Office hours are Monday-Friday, 7:00 a.m.-5:00 p.m.

There are approximately [illegible] employees at the Midvale, Utah facility.

UTMD has a current registration status as a manufacturer, contract manufacturer, specifications developer, repackager/relabeler, and initial distributor.

Ms. Karen A. Coleman, National Expert, Medical Devices, FDA, participated in this inspection. Both Ms. Coleman and myself were present on each day of the inspection.

On 2/24/03, credentials were presented to Mr. John R. Smith, Quality Manager, Mr. Ben Shirley, Vice President of Engineering and Mr. Kevin L. Cornwell, CEO and Chairman. The FDA-482 was presented to Mr. Smith, Quality Manager and Management Representative.

On 3/12/03, a FDA-483, Inspectional Observations, was issued to Mr. Cornwell in the presence of Mr. Smith and Mr. Shirley.

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

HISTORY

Written by CSO Chase-Off

UTMD was incorporated in the State of Utah in 1978. This Midvale, Utah location is the parent firm. [redacted] Mr. Kevin L. Cornwell, CEO and Chairman, is responsible for operations and all three locations.

UTMD has an extensive inspectional history including a 1995 inspection that was classified OAI and resulted in a Warning Letter. The firm was inspected in 1998; the inspection was classified NAI. The firm was again inspected 6/4/01-6/8/01. That inspection was OAI and resulted in a Warning Letter. A follow-up inspection to the Warning Letter was conducted 3/26/02-4/15/02. That inspection was classified OAI; however, no action has been taken regarding that inspection. A limited inspection was conducted 6/4/02-6/5/02. That inspection was conducted to collect further documentation requested after review of the 3/02 inspection.

Objectionable conditions noted in 1995 included: failure of the DHR to meet the requirements of the DMR; inadequate procedures to control finished product release, final inspection, and manufacturing; failure to follow procedures; no failure investigation for each device specification; inadequate failure investigations on complaints; actual test data were not included in the failure investigation; no processing procedures for molding; no validation studies for injection molding; no documentation on the QA IUP final test device used in complaint evaluation.

The 1998 inspection was classified NAI; however, verbal warnings were given regarding the inability of the firm's [redacted] software system to capture and trend similar data; not following the firm's incoming sampling schedule; QA procedures did not address the default sampling plan and, the firm's procedure for purchasing controls did not include scheduled review of the vendor.

Objectionable conditions noted in 2001 included: CAPA procedure did not include the requirement to analyze sources of quality data; not all quality data were being analyzed; failure to initiate corrective and preventive action; manufacturing procedure failed to ensure that devices met the approved design specification; lack of validation for the over mold primer application; non-conforming materials procedure did not include a determination for the need for an investigation; non-conforming materials procedure was not always being followed; failure to certify the use of

electronic signatures; failure to validate electronic records systems; and use of sampling plans that were not based on a valid statistical rationale.

Objectionable conditions noted in 2002 included: lack of sterilization validation; incomplete corrective and preventive actions; inadequate DHRs; failure to capture and review all relevant sources of quality data; lack of documented statistical rationale; inadequate change control procedure; failure of internal quality audits to identify deficiencies; inadequate non-conforming materials procedure; inadequate internal audit procedure; and, lack of software validation.

Discussion of the current inspectional findings can be found in the Objectionable Conditions section of this EIR.

INTERSTATE COMMERCE

Written by CSO Chase-Off

Annual sales of UTMD products are approximately [redacted] Approximately [redacted] of the finished devices are distributed in interstate commerce.

Promotion includes a direct sales force, promotional catalogs and the internet, www.utahmed.com.

Not all promotional materials were obtained during the current inspection but can be found in the previous inspection report of 3/02.

JURISDICTION

Written by CSO Chase-Off

UTMD manufactures devices for labor and delivery obstetrics; neonatal intensive care; blood pressure monitoring; gynecology; urology; and, electro surgery. Devices may or may not be sterilized. Further, UTMD distributes some vendor items which it does not further manufacture.

A list of UTMD's FDA listed products is included (Attachment R1.1-1.4), as well as a list of UTMD's 510k holdings (Attachment R2.1-2.4).

The [redacted] devices include:

Intrauterine Pressure Catheters (IUP) – 400/450/500/550/600/650/700/750

Deltran – pressure transducers

ABC Kits – arterial blood collection systems that include a Deltran device

Velvet Touch – vacuum system for delivery

Finesse – electrosurgical and smoke evacuation system

Liberty – pelvic floor stimulator

Umbilicath – neonatal umbilical catheter
Various electrocautery loops for LETZ and LEEP procedures

Not all product catalogs were collected during this inspection but may be found in the previous establishment inspection report of 3/02.

Labeling was collected for the Intran Intrauterine Pressure catheter (IUPs); the IUP 500 model (Exhibit R1.1-1.3). That labeling includes the device user's manual (Exhibit R2.1-2.24).

No other labeling was collected. Labeling for all products UTMD manufactures was included in the previous inspection report of 3/02.

Documentary sample 199272 was collected to document interstate commerce and deviations from the QSR.

RESPONSIBILITY

Written by CSO Chase-Off

On 2/24/03, credentials were presented to Mr. John R. Smith, Quality Manager, Mr. Ben Shirley, Vice President of Engineering and Mr. Kevin L. Cornwell, CEO and Chairman.

I requested to present the FDA-482 to Mr. Cornwell, who declined and referred me to Mr. Smith. Mr. Smith was identified by Mr. Cornwell as UTMD's Management Representative.

Mr. Smith and Mr. Shirley were present throughout the inspection. Messrs. Smith and Shirley provided requested documentation, answered questions and provided tours of the facility. Mr. Cornwell was present at the opening of the inspection and during the close-out discussion at the end of every inspectional day. Messrs. Smith, Shirley and Cornwell were present during the presentation of the FDA-483 and the close-out discussions on 3/12/03.

NOTE: Daily close-out meetings were audio taped. Those tapes are included as Exhibits R179.1-179.6 to this Establishment Inspection Report (EIR) (**Original EIR only**).

Mr. Kevin L. Cornwell – CEO and Chairman – Mr. Cornwell is also the firm's President and Secretary. Mr. Cornwell is the firm's Management with Executive Responsibility. By his own admission, Mr. Cornwell is personally involved with the day to day operations of the UTMD. Mr. Cornwell is a member of the [redacted] Mr. Cornwell stated that he participates directly in control of the firm's corrective and preventive action procedures, complaint review, MDR decisions, and tracking and trending of quality data. Mr. Cornwell reports to the Board of Directors.

Mr. John R. Smith – Quality Manager – Mr. Smith is the firm's Management Representative. Mr. Smith received the FDA-482 on 2/24/03 and participated in each day's activities. Mr. Smith answered questions, provided documentation, and provided tours of the facility.

Mr. Smith's duties include management review, complaint and failure investigations, review of MDRs, control of the corrective and preventive action system, document control, overseeing the non-conforming materials system, process control and review, including sterilization, approval of device history records and device master records, conducting internal audits, handling recalls, and making 510(k) submissions.

Mr. Smith is responsible for the compliance activities of the UTMD

Mr. Smith reports directly to Mr. Cornwell.

Mr. Ben Shirley – Vice President of Engineering – Mr. Shirley directs engineering with regards to product development and design control. Mr. Shirley also participates in the engineering activities involved with product manufacturing and complaint evaluations. Mr. Shirley reports to Mr. Cornwell. Mr. Shirley was present each day of the inspection. He answered questions and provided documentation and tours of the facility.

– Manufacturing Engineer – is involved in conducting failure analysis on complaints and according to Mr. Shirley is involved in complaint analysis. Due to UTMD's policy, was not available for a personal interview, although one was requested. It is unknown to whom reports.

An organizational chart was provided at my request. However, Mr. Cornwell would not provide names to accompany the position descriptions stating that he had a responsibility to keep that personnel information confidential. The chart is provided as part of SOP, DR-HR-06, Human Resources Administration, which also contains position descriptions (Exhibit R3.1-3.17).

The 2001 Annual Report is also provided (Exhibit R4.1-4.32). At the time of this inspection, the 2002 Annual Report had not been completed.

The 2001 Annual Report identifies the following Officers and members of the Board.

Mr. Paul O. Richins – Chief Administrative Officer and Vice President
Mr. Greg A. LeClaire – Chief Financial Officer
Mr. Mark A. Lanman – Vice President of Sales

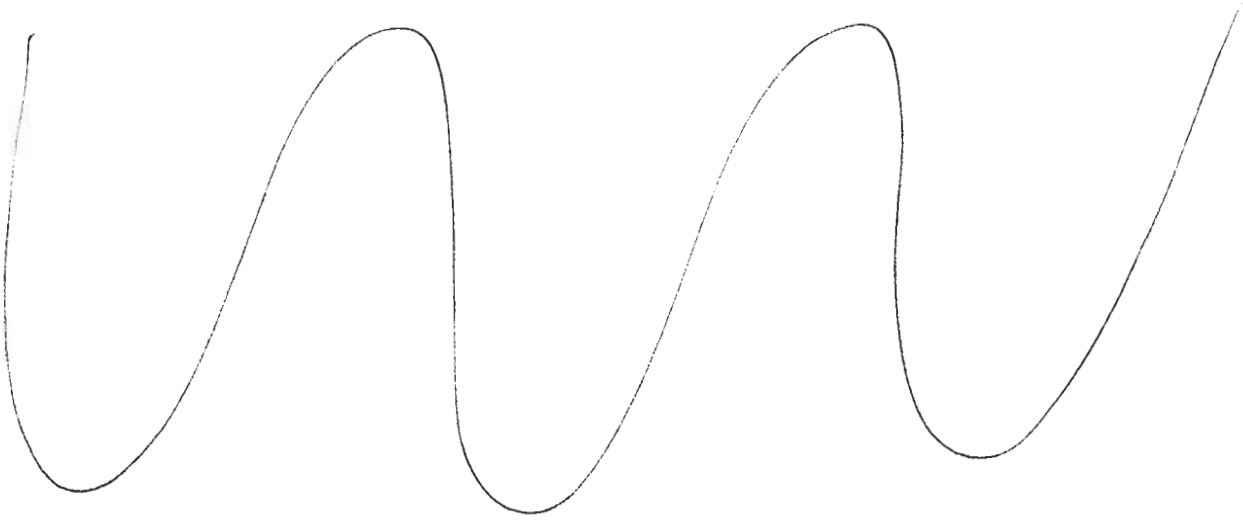
There are no labeling agreements at this firm.

Post-inspectional correspondence should be directed to Mr. Kevin L. Cornwell, CEO and Chairman, Utah Medical Products, Inc., 7043 South 300 West, Midvale, Utah 84047.

MANUFACTURING / DESIGN OPERATIONS

Written by CSO Chase-Off

The facility is a two story building located in a business park in Midvale, Utah. Manufacturing operations are located on the first floor while business offices are located on the second. Manufacturing occupies approximately square feet.



The following operations were observed in detail during the inspection: IUP manufacturing (not packaging), injection molding and extrusion, loop manufacturing, EA assembly operations and Finesse trouble shooting.

This was a Level III QSIT inspection conducted as a follow-up to an OAI inspection of 3/02 and a Warning Letter issued in response to a 6/01 inspection.

UTMD's Quality Manual is included (Exhibit R5.1-5.26).

Documents reviewed in the *Management Responsibility* subsystem included: Quality Plan, Internal Audit SOP and audit plans, and the agenda for the [redacted] management review meeting.

Documents reviewed in the *Design Control* subsystem included a design change to IUP catheters resulting in the IUP 500/550 model being produced. A design change [redacted] for the IUP x00 models was reviewed. Further, a design change in [redacted] and materials was reviewed [redacted] Design control documents for the [redacted] Project were also reviewed and collected. SOPs for design control were reviewed. Procedure [redacted] Rev. [redacted], For the Development of Products, [redacted] and Form [redacted] Rev. [redacted], Project Checklist were specifically reviewed.

Documents reviewed in the *Production and Process Control* subsystem included review of device history records (DHR) for IUP, Deltran, ABC Kits and Finesse electrosurgical units. The device master record (DMR) for IUP catheters was reviewed as was the DMR for Finesse. Molding and extrusion processes were witnessed as was the full assembly of IUP catheters. The EA room was visited and the ~~~ system was reviewed. SOPs were reviewed for the production processes that were observed. Further, document control and software systems were reviewed. The firm maintains a General Operational Procedures, SOP, ~~~ which outlines the main procedural documents UTMD operates from (Exhibit R6.1-6.7).

Validations reviewed included sterilization (bioburden, comparative resistance, LAL), real time packaging studies and software. Validations for extrusion molding and injection molding were requested but not provided.

~~~

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 firm does not make any devices subject to Tracking requirements. There were no corrections and removals. One recall was initiated and was reviewed (See Complaints).

MANUFACTURING CODES

Written by CSO Chase-Off

~~~

COMPLAINTS / PRODUCT DEFECTS

Written by CSO Chase-Off

UTMD initiated a product recall, Z-0025-3, dated 9/13/02 for CMI Velvet Touch Vacuum Extractor Cups due to chrome flaking off of the handle of the product (Exhibit R7.1-7.18). The handle is a vendor part. Documents were reviewed for communications between UTMD and the vendor; corrective action was taken by the vendor and was to be verified by UTMD. The chrome plating was flaking due to improper cleaning of the substrate prior to the chrome application.

No objectionable conditions were noted regarding the recall.

The CDRH MAUDE database revealed the following:

MDR report 415545 for the Velvet Touch Vacuum Extractor Cups in use during a C-Section procedure. (Attachment R3.1-3.3)

MDR report 395123 for CMI Tender Touch vacuum cup caused a subgaleal hematoma. (Attachment R4.1-4.3)

MDR report 394338 for ABC-528NP for a tubing separation that caused blood loss. (Attachment R5.1-5.3)

MedWatch 403866 for Cautery Extender that sparked causing a superficial burn to the patient. (Attachment R6.1-6.2)

MedWatch 404356 for Epitome 4" Ceramic Bovie Tip that broke in use. The tip was retrieved from the patient. (Attachment R7.1-7.2)

MedWatch 395849 for Utah Loop, portion of the loop broke off while removing the loop at the end of the procedure. (Attachment R8.1-8.2)

MedWatch 385272 for LETZ loop electrode, during a procedure the wire broke and was not found. (Attachment R9.1-9.2)

MedWatch 389141 for Finesse Electrosurgery Smoke Evacuation that stopped working during a LEEP procedure. The top and bottom cut was made and the patient had to be taken to surgery to finish the procedure. (Attachment R10.1-10.2)

NOTE:

MedWatch 385272 was reviewed (Attachment 9.1-9.2). The complaint investigation, revealed that the loop wire was missing and the handle was melted and charred (Exhibit R99.1-99.21). This item is discussed as 483 Observation #6B.

MedWatch 389141 was reviewed (Attachment 10.1-10.1). The complaint investigation and MedWatch report reveals that the patient had to be moved to surgery in an adjacent medical

facility for the procedure to be completed (Exhibit R98.1-98.12). This item is discussed as 483 Observation #6A.

OBJECTIONABLE CONDITIONS

Written by CSO Chase-Off

The investigator primarily responsible for each Observation has provided the supporting text. Each Observation is noted as to the author.

On 3/12/03, an FDA-483, Inspectional Observations was issued to Mr. Kevin L. Cornwell, CEO and Chairman, Utah Medical Products, Inc. Individuals present for the close-out meeting included Mr. Cornwell; Mr. John R. Smith, Quality Manager; Mr. Ben Shirley, Vice President of Engineering; Ms. Karen A. Coleman, Investigator; and myself, Ms. Ricki A. Chase-Off, Investigator.

The close-out meeting was audio taped in its entirety. Those tapes are included as Exhibits R180.1-180.6 to this Establishment Inspection Report (EIR). (Exhibit contained in the Original, CDRH and SLC-RP copies of the EIR only.)

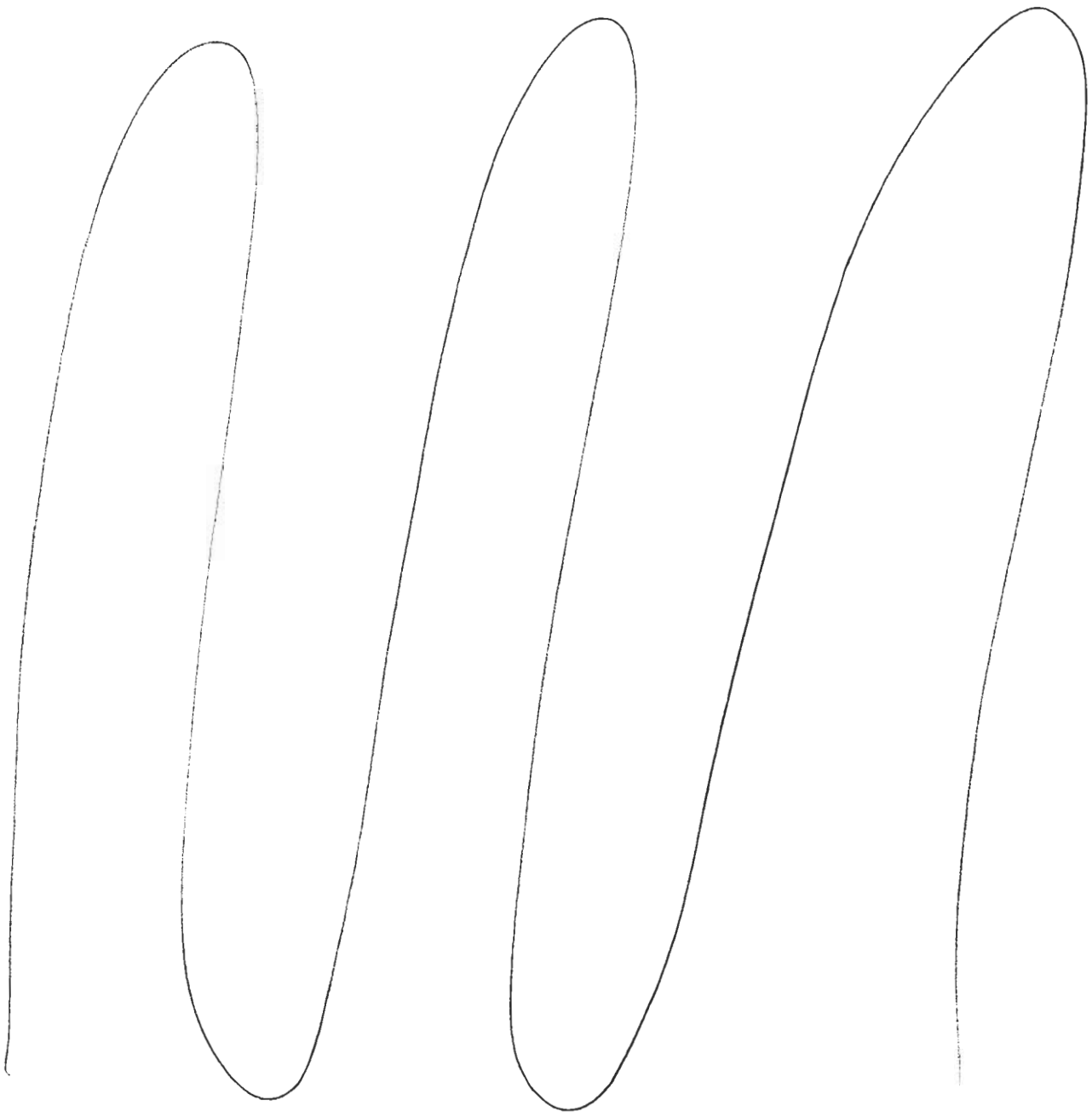
Mr. Cornwell elected to annotate some, but not all, of the observations listed below. Where annotations are blank, Mr. Cornwell requested no annotation be made.

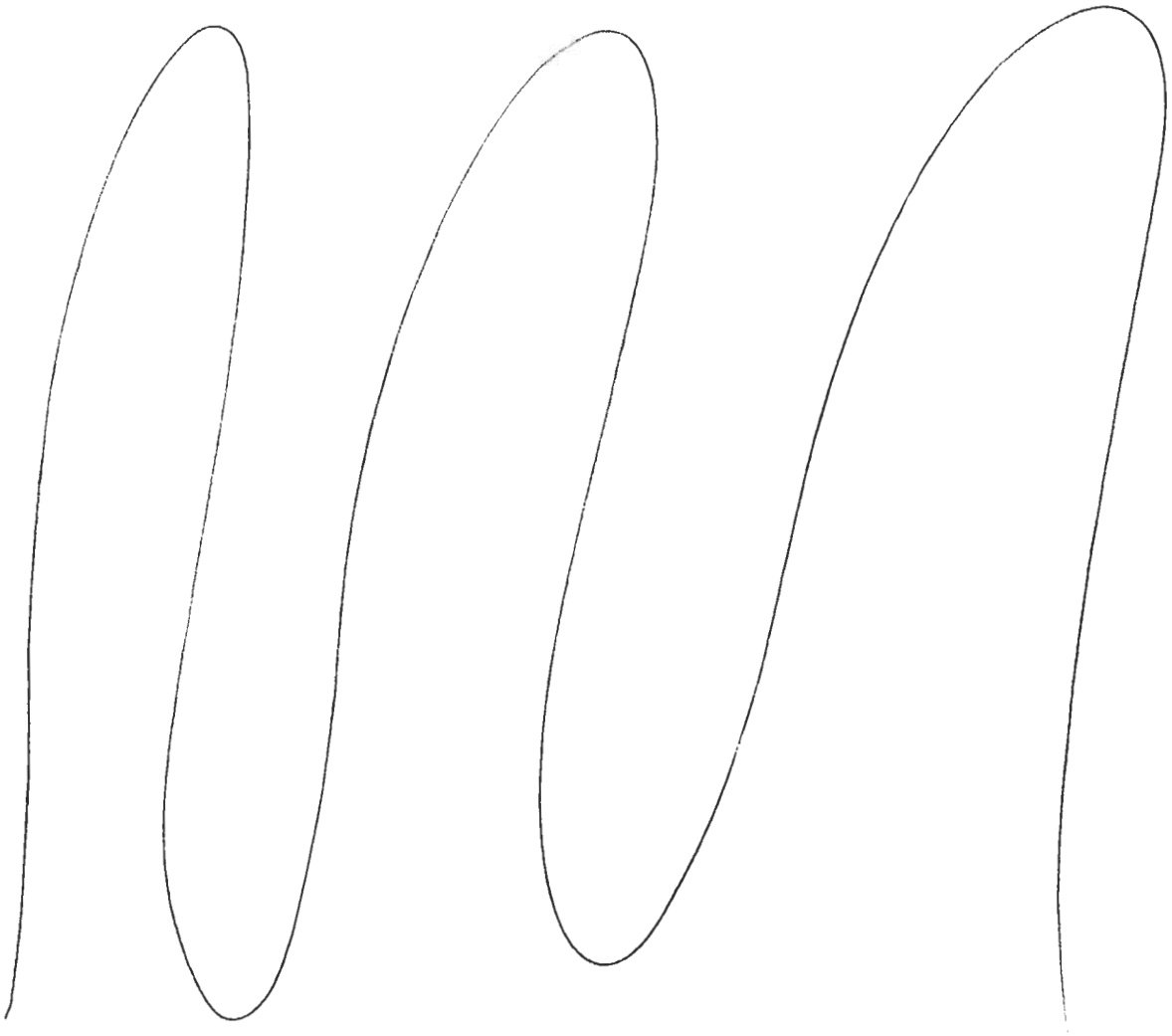
Observations listed on form FDA 483

OBSERVATION 1

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,





Reference: 21 CFR 820.75(a)

Observations 1A, B, and D were made by Investigator Coleman.
Observations 1C, E and F were made by Investigator Chase-Off.

Relevance:

1.A.1. Systemic problems apply to all sterile devices. Firm does not have scientific evidence needed to support their use of Process Challenge Devices [Master Product BI's] for testing and release in routine sterilization because of problems with their comparative resistance studies (CRS). They are depending on old studies of discontinued devices that have failed to demonstrate the inoculated site or BI location was the most difficult to sterilize and/or failed to perform a CRS on a new product [see FDA 483 item A 2].

1.A.2. Firm had no scientific data to support rationale that [redacted] was similar to [redacted] for adding it to cycle [redacted]. There is no validated sterilization cycle for this product.

1.B. Applies to all devices labeled as non-pyrogenic. The device processing is not completed until after sterilization processing; therefore, LAL testing should not be performed until the device has completed sterilization processing activities.

1.C.1. Test Protocol, [redacted] was written to be used for Real Time Packaging and Integrity Tests for all of the medical devices that UTMD manufactures.

1.C.2. Test Report, [redacted] applies only to devices packaged in [redacted] pouches or devices in [redacted]

1.D.1. Lack of validation for all extruded parts. Firm had previous 483 observation for lack of validation on injection molding. Molding is a process that cannot be fully verified by subsequent inspection and test.

They are supposed to validate molding processes and have documented approved operating parameters (including set-up parameters) in their controlled document system. The practice of copying the set-up parameters from the previous sheet does not assure the operating parameters are being adequately monitored and controlled. Without approved operating parameters from validation they cannot be sure the operating parameters are not drifting or changing over time as they are used.

The firm could not locate any validation data prior to end of the inspection.

1.D.2 System wide problem for lack of validation of all injection molded parts. Molding process should be validated. This is a repeat FDA-483 Observation from 1995 (Attachment 14).

1.E. This observation applies to IUP catheters only. There is no documentation to support a [redacted], although, the DMR allows for [redacted] However, UTMD has not had a sterilization load failure that has resulted in the necessity for a [redacted] The observation goes to the lack of validation for such a process and to the DMR.

1.F. This observation relates to all models of IUP catheters with the slip-on tip. Complaints were received in 2002 for leaking at the tip/catheter junction. The gluing process has not been validated.

Discussion with management:

1.A.1. Mr. Smith - We have lots more Deltran studies done.

PURGED

Mr. Shirley – I got what I asked for
Ms. Coleman – So noted

Mr. Smith referred to the study and said it was inaccurate. See IUP 200 (discontinued device) has same sort of configuration as tubing IUP 400 and same locations. The study doesn't understand why this is inadequate. In the purpose of the study was not to demonstrate most difficult to sterilize location that was the study. has same purpose as He said there were several positive … we suspected under the cap – that turned out to be the case.

Mr. Cornwell promised new test results. The IUP 500 comparative resistance is being done with inoculation at previous sites and locations I recommended.

1.A.2. Mr. Smith says did not exist in They followed what they understood to be required at that time after taking a logical look at the product and adoption in to the cycle. Mr. Cornwell says the Intran is sterilize. Mr. Shirley said they did evaluate it. Mr. Cornwell says not withstanding they are doing it now.

1.B. See Additional Information Section of this EIR.

1.C.1. Mr. Cornwell asked for a reference, I told him he could find a Guidance document on FDA's website that would assist him in understanding packaging qualifications and shelf life studies. I distinguished between packaging qualifications and real time shelf life studies for medical devices for their understanding.

1.C.2. I explained that it is expected that firms will conduct real time studies to support accelerated aging studies that have been performed.

1.D.1. Mr. Ben Shirley verified they had not been able to locate any extrusion validation work in the archives to date. Mr. Cornwell said this process has been in use since .

1.D.2. During the closeout discussion Mr. Ben Shirley stated this was the same as the last one. They instigated it many years ago and have not been able to find it in the archives.

1.E. Mr. Shirley asked if it was my opinion that they needed to have the raw data and the lot that went on test. I told Mr. Shirley that they needed to demonstrate to me that the devices actually went through cycles and that the way to demonstrate that is to provide the raw data test parameters) and to show me that the lots were manufactured according to procedures established at the time of the study, as real or simulated use product.

Mr. Shirley asked if I was saying I didn't trust the engineers providing the document. I told him I was explaining what was necessary in the validation.

Mr. Cornwell stated that it wasn't a sterilization issue, it was a biocompatibility issue.

Mr. Smith stated that the study was not intended to be validation of the cycle. It was written to be a product qualification. I stated that I understood Mr. Smith's point; however, no other documentation was provided to support the current justification for ~~~ cycles as allowed in the DMR.

Mr. Cornwell stated that the firm is currently addressing ~~~ exposure on the studies being conducted on the ~~~ device for ~~~

Mr. Shirley stated that they tried to locate the test data to support the Test Report but could not locate those records. Mr. Cornwell stated that the intent is to find the applicable records for items 1.E.1. and 1.E.2. and that item 1.E.3. will be corrected as part of the work the firm is doing on the IUP-500 device for sterilization.

1.F. Mr. Shirley stated his opinion that the Test Reports and Test Protocols provided for qualification of the ~~~ (Exhibits R17.1-17.3 and R18.1-18.11) support validation of the gluing process itself. Mr. Shirley stated that there is nothing to correct for this Observation. According to Mr. Shirley, it is a matter of opinion that the process was not validated.

Additional details of the observation:
UTMD maintains a general SOP for Manufacturing Process Qualification and Validation, ~~~ (Exhibit R8.1-8.3).

1.A.1. Firm provided the Comparative Resistance studies (CRS) listed in the Observation above. The firm used these studies to support their use of a ~~~ for testing and release of devices after ~~~ sterilization.

The use of a process challenge device for testing and release from sterilization requires scientific data to show that the challenge device is more difficult to sterilize than the actual device it is replacing. There must be valid scientific evidence showing that the device/s have been tested (inoculated with spores or spore strips) to prove where the most difficult to sterilize locations are in the device. A firm must prove which product within a family group is the most complex and difficult to sterilize or they have to perform a CRS on every device. If there are injection ports, caps (vented or non-vented), and tubing all of these locations [including various points along the length of the tubing lumen] must be tested to prove the most difficult to sterilize location.

I asked if the firm had a study for the ~~~ that was more recent than the ~~~ study. I was provided with lab study number ~~~. On 02/28/03 Mr. John R. Smith verified that this is the latest CRS on the ~~~ devices. This device has a dual lumen [see lumen diagram in **Exhibit K 1.1** the upper round section is used to pass the wiring through it and the lower lumen is used for amino fusion [inject fluids and/or medications or drawn up fluids]. The lower portion of the tubing has an outer sheath that is used to help insert the device then it can be pulled back exposing

the holes for amino fusion. [See device on the front of the IUP brochure at the top of the page **Exhibit K 2.1**] The firm says the tubing is not cut into pieces because the upper lumen has wires with no patient contact. However, the inner lumen of this device is used to draw up amino fluid or to pass fluids through it.

The longer the tubing length and the more it is coiled the more important it is to test the inner lumen and the coiled configuration to determine the most difficult to sterilize locations. The tubing had two holes in it that are above the tip. When the outer sheath is down for insertion it is covers these holes.

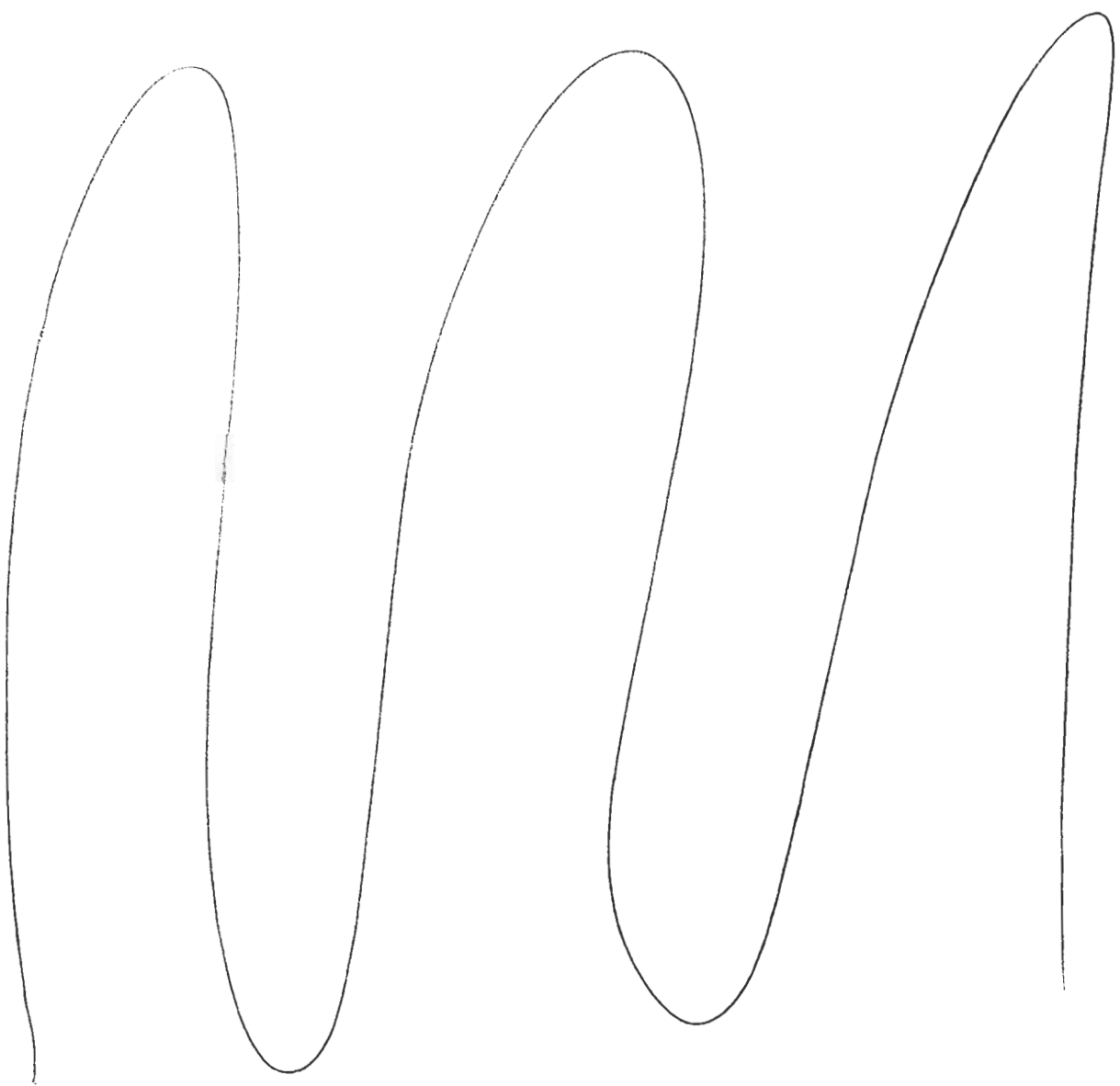
Based on questions I asked and concerns I expressed regarding the inoculation sites the firm provided additional studies for review. I also noticed there were different syringe sizes so they provided another study that they said supported the use of various syringe sizes.

The following changes have occurred in the IUP Device since [redacted] and would require a new comparative resistance study: [redacted] [redacted] was added to the sterilization cycle with no comparative resistance study [see FDA 483 item 1.A.2. discussion].

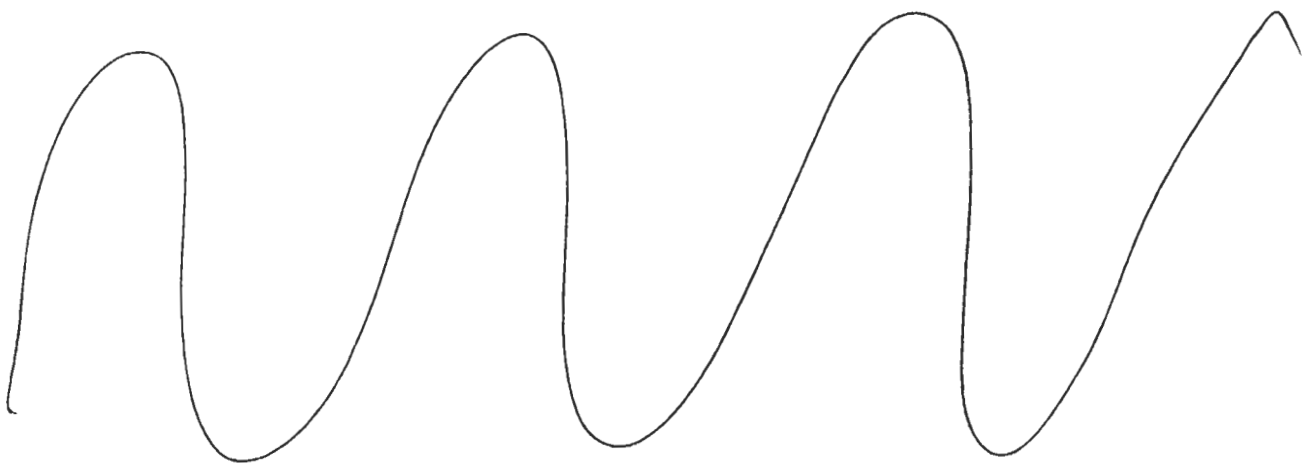
On 3/3/03 Mr. John Smith informed me they had a data file of the comparative resistance studies I requested a copy. He said there might be some older ones they had missed. He verified this list included all the recent studies. I highlighted the studies reviewed in yellow. **See Exhibit K 3.1**

The Table below provides information on the comparative resistance studies identifying the year, device/s used in the study, the lab study number, the size of the syringe [or process challenge device (PCD)], spore count used [either as spores or BI's]. Comments on why the study is inadequate to support the current [redacted] Sterilization cycle.

[redacted]



specification. He said it was in their validation work and he did not see any reason why it should be have to be an approved specification. Then later on he provided the documents attached as Exhibits K 11, 12, and 13. They also have a ~~~ used in validation work referred to as ~~~

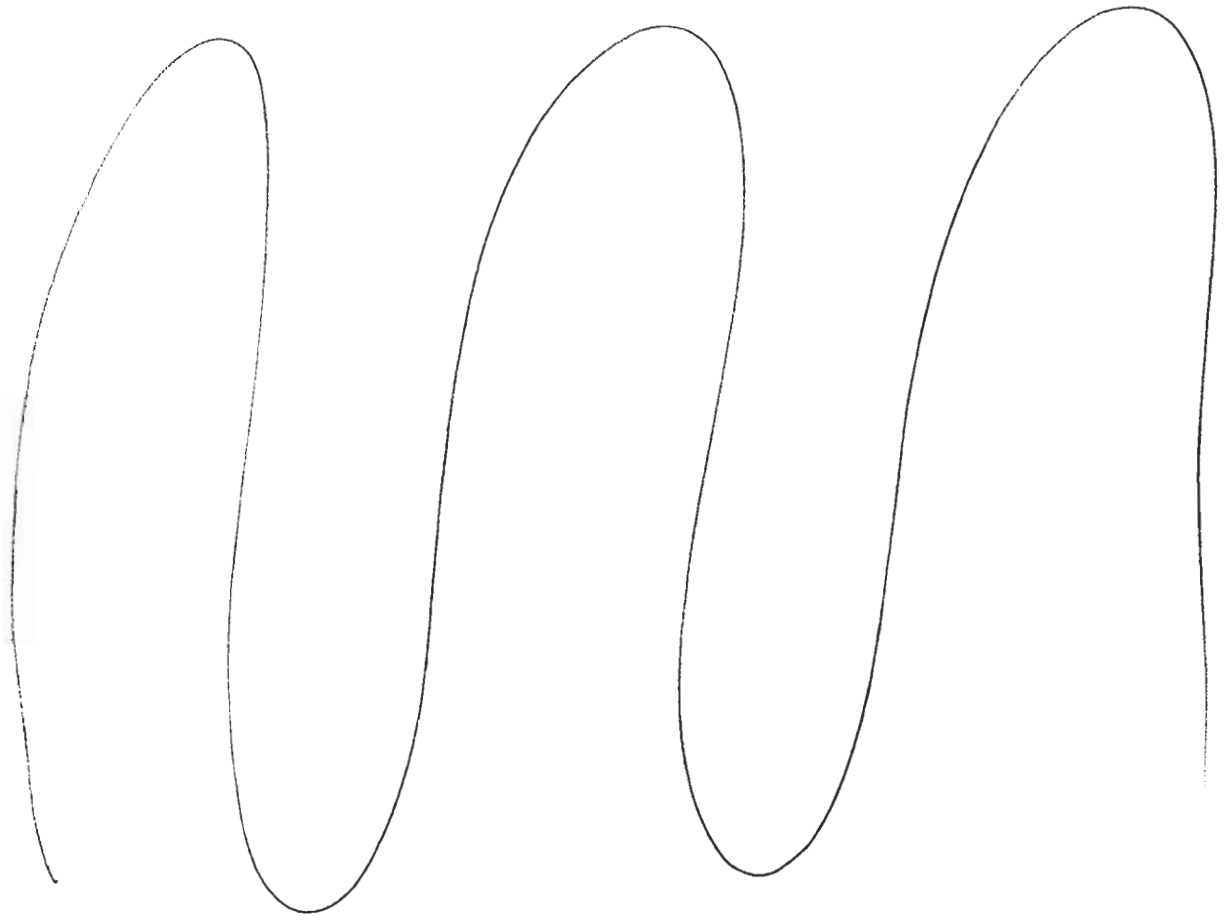


NOTE: After reviewing the comparative resistance studies, several of the firms procedures, and forms associated with sterilization I noticed that they have numerous terms that all refer to the Process Challenge Device ~~~ used in the sterilization cycles which includes the BI for testing and release in sterilization. It may be referred to as the Master Product, Master Product BI, Biological Indicator, Master Product Biological Indicator Sample, the BI-Sterility Test Unit, Master Product Samples, and/or Process Challenge Device etc.

Exhibit K 19.1-K 19.3 is a copy of the last contract signed with the contract sterilizer in ~~~. According to Mr. John Smith they are ~~~ ~~~ When I asked about the ~~~ ater during the inspection he said this was something they could not complete while they were having an FDA inspection.

~~~ STERILIZATION, ~~~ requires revalidation assessment on ~~~ ; and revalidation when ~~~ . Section 5.1 of this procedure addresses ~~~ The procedure includes ~~~ Sterilization but the firm is ~~~
See Exhibit K 20.1-K 20.4.

Since there are issues with the comparative resistance studies reviewed I have provided a table to give a brief summary of the validation work reviewed during the inspection.
~~~



1.A.2. The Intran 500 device [IUP 500] has an amino view port that extends off the side of the device at the injection port location of the IUP 400 device [see Exhibit K 2.1-K 2.4 IUP Brochure]. This view port can be used to determine the color of the amniotic fluid or as an injection site for fluids and drugs if needed. This adds more connection sites and increases the complexity of sterilization for the device.

The firm's own design review indicates they did not perform a comparative resistance study. See **Exhibit K 25.1-K 25.4** Final Design Review dated K 25.3 under

Sterilization states [illegible]. See **Exhibit K 26.3** [illegible] Final Design Review Summary, dated [illegible] under "Sterilization" which states ' [illegible]

Additional information from the design review is found in **Exhibit K 27.1-K 27.3** showing a review of the Failure Modes, Effects and Criticality Analysis (FMECA) for the "View Port Assembly" potential failure mode. "Sterility compromised" had a Risk Priority Number (RPN) of 54. The cover memo dated ' [illegible] indicates there were only [illegible] numbers RPN's [illegible] that require additional evaluation. ' [illegible] dated [illegible] was the procedure used to assign codes for this analysis. [see **Exhibit K 27.4- K 7.9**]

I asked Mr. John Smith if they had any of the following tests on [illegible] comparative resistance study, current bioburden test, sterility test of the device from a validation run. On 03/04/04 Mr. John R. Smith confirmed they did not find a comparative resistance study on the [illegible] device. He provided lab report [illegible] for the bioburden test. The data in this report was from the AAMI Method 1 Dose Audit performed in the fall of [illegible] [see **Exhibit K 28.1-K 28.15**].

Mr. John Smith verified on 03/05/03 that the [illegible] was not included in any of their physical validation runs for sterilization, yet it was added to [illegible] Sterilization without a comparative resistance study (CRS) or device sterilization test. Failure to have comparative resistance studies on more complex models or complex combinations means there is no scientific data to support the use of a PCD. Therefore there is no scientific evidence to support adopting it into the [illegible]

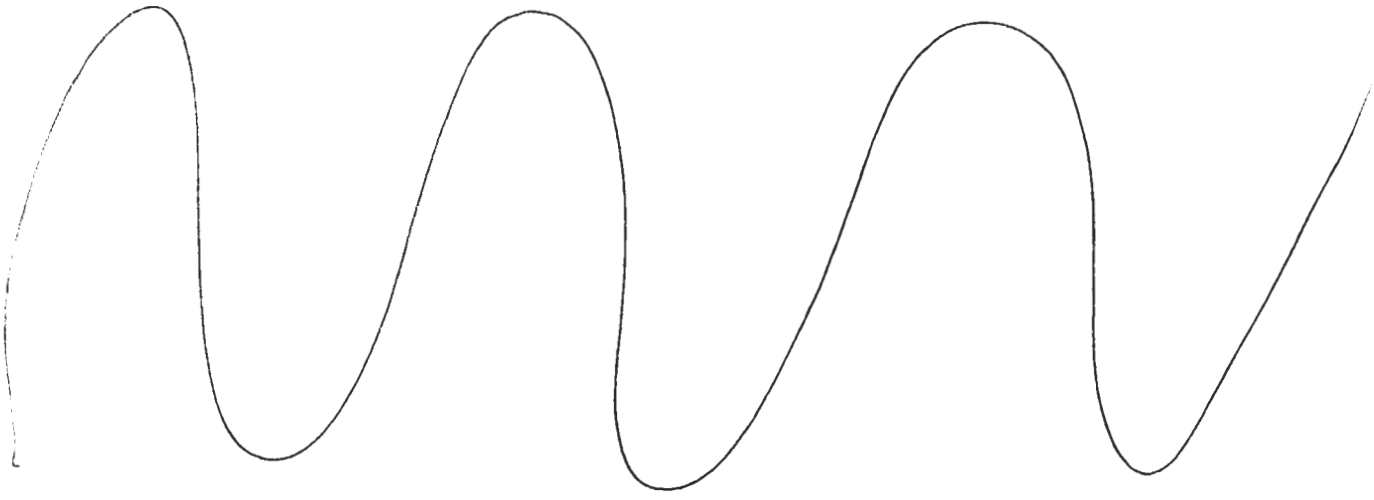
On 03/05/03 during the end of day discussion Mr. Cornwell said they were having the [illegible]

1.B. On 03/05/03 Mr. John R. Smith verified that LAL testing was now performed on their devices prior to sterilization as per [illegible] [See **Exhibit K 14.1-K 14.6**] Mr. John Smith said it was done on the advice of their laboratory microbiologist [illegible] because the test is to look for the presence of gram negative bacteria so "it doesn't matter whether it is done pre or post sterilization". I asked him for the date when they made this switch to pre sterilization LAL testing. Mr. Smith reported it was in [illegible] Mr. Smith was asked to provide me information on the LAL change from post sterilization to pre sterilization.

The information I was provided, CHANGE PROPOSAL [illegible], is attached as **Exhibit K 29.1-K 29.13**. The CHANGE PROPOSAL [illegible]. REASON FOR CHANGE states [illegible] The document that was changed is attached to it as [illegible]

[see **K 29.10 and K 29.11**] telling the employee to prepare the Laboratory Sample Submission Form for the LAL Test Samples and [illegible] is also attached to the change proposal. Revision [illegible] **Exhibit K 29.4**] shows additional information lined out for the LAL testing and [illegible] was changed to read [illegible]

The exhibits in the Table below are the LAL reports on devices from a sample of [illegible] of the DHR records reviewed during the inspection.



During the FDA 483 discussion on 3/12/03 Mr. Cornwell stated the issue seemed clear. Mr. John Smith said he believes what they are doing is adequate. He said prior to the change they looked at their data [illegible] and found they had no test failures from [illegible] tests. [illegible] they have done [illegible] tests without any failures. He stated they have not had any positives since he came here in [illegible]

I reminded the firm that these devices were labeled as non-pyrogenic and that the testing should be perform after sterilization. [See **Exhibits K 36.1- K 36.7** and **K 37.1- K 37.5** work order [illegible] with labeling examples]

NOTE: The data review referred to by Mr. John R. Smith for the LAL change was not provided to me when I requested information on the LAL post – pre sterilization testing change. The firm chose not to provide this information for FDA review during the inspection. If this data review was performed in conjunction with the change proposal it should have been mentioned on the form and attached with the document revisions. I reminded the firm early during this inspection that if they had any data to negate a possible 483 issue they were to make it available for our review even if I did not ask for it by the name. Without reviewing the information and asking additional questions I do not know when it was actually prepared by the firm. This is an example of information the firm says they had that was not provided nor did they mention it even existed.

1.C.1. I asked Mr. Smith and Mr. Shirley if UTMD had done any shelf life studies on its medical devices, specifically for the IUP catheters. I was provided with Test Protocol, [redacted] (Exhibits R9.1-9.5 and R10.1-10.9).

[redacted]

A review of the TP revealed that the TP was not complete in that it did not contain a storage plan for the devices, simulation of shipping and handling stresses and did not identify the organizational units responsible for the testing.

Further, the TP is not for shelf life studies of devices. The TP is for testing the shelf life of the packaging materials.

1.C.2. Test Report, [redacted] (Exhibit R10.1-10.9), reports the finding of packaging tests that were done on [redacted] pouches that had been retained for [redacted] The test report does not state which lots of products were placed on test, what the environmental storage conditions were and did not including shipping and handling tests on the packages.

Currently, Gesco devices, such as Umbilicath are packaged in the [redacted] DHRs (work orders) were collected as examples [redacted] of Gesco products with 5 year expiration dates.

Again, the Test Report did not evaluate the shelf life of the devices; it only examined packaging characteristics.

1.D.1. The following Exhibits were collected related to extrusion molding operations:

Exhibit K 38.1is a diagram of the molding production area showing the location of the extruder near the bottom on the right side.

Exhibit K 39.1 – K39.3 ...Work Order on **K 39.1** of the work order states '

Exhibit K 40.1-K 40.7, , EXTRUSION SET-UP, . A review of this procedure revealed it does not contain set-up parameters. It does give information on making adjustments for +/- tolerances on the laser mike settings but no information on what the actual settings are for the different sizes of tubing it should measure. There are no other references in it for the operational set-up parameters for temperature zones, die melt, screw RPM, pressure, puller/cutter speeds other than to check the set-up sheet.

An example of the EXTRUDER SET-UP sheet and EXTRUDER RUN SHEET being used in production on are attached see **Exhibit K 41.9 - 41.12.** These are part of **Exhibit K 41.1- K 41.12** in EXTRUSION RUNNING PROCEDURE, dated They are identified in the top right hand corner as part of this procedure. A review of the run instructions in this procedure states at of this Exhibit are examples of pages that were in use during production with the *hand recorded set-up data.*

On 3/5/03 Mr. Ben Shirley, V. P. of Engineering verified that these extrusion set-up parameters are copied from the last set-up sheet and they are not referenced in a procedure or SOP.

Firm is using Statistical Process Control for their molding operations. The operators are filling out an Attribute Inspection Form during processing. The forms from extrusion molding , were reviewed for the Intran Plus, Dual Lumen Tubing, 30.5 in. /Part Number 2500/for work order dated No defects were recorded on these forms. The sampling interval is every for a sample size of .

Exhibit K 42.1- K 42.6 , EXTRUSION CLEANING PROCEDURE, dated provides instructions on shutting down the extruder, cleaning the die, and shut down of other equipment.

1.D.2. The lack of validation for injection molding is a repeat observation noted on the previous FDA 483's for 2001 and 1995. During this inspection the firm was asked to provide any validation data they had for injection molding of the female luer. The female luer is one of the components used on several devices made by the firm. They were given additional time to look for it when it

was not provided the day that I asked for it. Mr. Ben Shirley verified via phone call on 03/7/03 that they had not been able to locate any validation documents in their archives. This was reconfirmed during the closeout meeting.

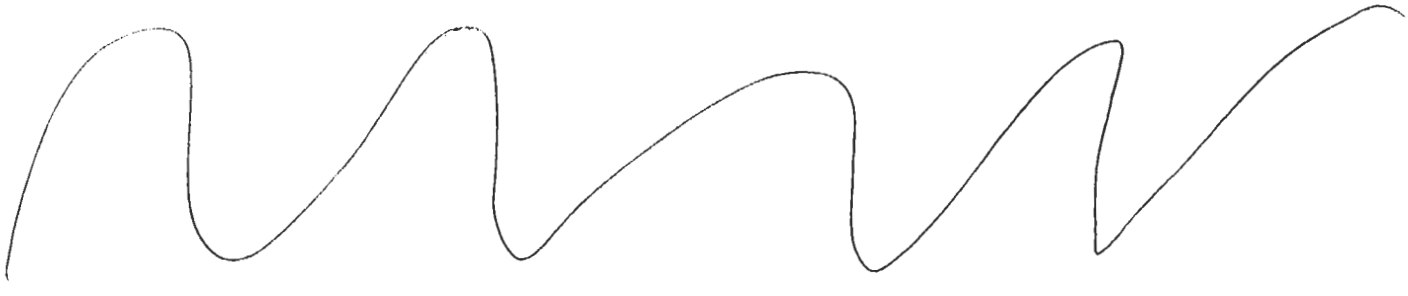
The following documents were collected related to injecting molding:

Exhibit K 38.1 is a diagram of the molding production area it shows the location of the [illegible] On 3/4/03 I observed injection molding operations on Work Order [illegible] **Exhibit K43.1- K 43. 4** shows an example of a work order [WO] traveler and pick list for WO [illegible] or [illegible]. DESC : [illegible] I verified that the set-up parameters for the process were specified in the work order on the MOLDING SET-UP SHEET for machine number [illegible] that was in use. [**see Exhibit K 44.1-K 44.2**]. However, note under the Hydraulic Ejector section [illegible] but the set point is recorded as [illegible] This was not discussed with the firm.

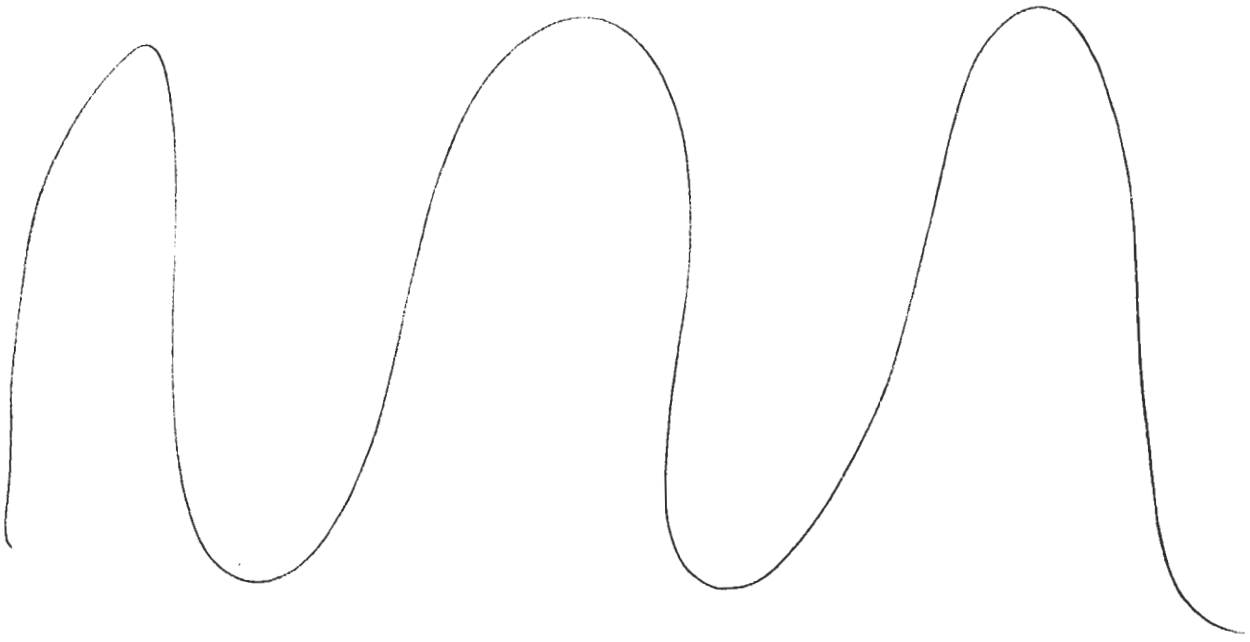
Exhibit K 45.1 is an example of the RUN SHEET in use for part number [illegible] on machine number [illegible] with mold number [illegible] [**Exhibit 55.1-55.3** is the Run Sheet Form Specification]. The IN-PROCESS MOLD MAINTENANCE sheet is attached as **Exhibit K 46.1**.

The SOP's related to injecting molding set-up and monitoring operations, [illegible]; RUN SHEET-MOLDING were also collected but they are being included in the exhibits where applicable to the injection molding of the female luer.

During the inspection the firm was asked to provide a copy of the validation for the female luer molding operations. They did not provide any validation data or study for review as requested. I requested a set of documents for the injection molding of this part. The following is a list of these documents in the order as they first appear on the manufacturing Work Order for the Female Luer Body:



PURGI



1.E. While reviewing the for IUP devices (Exhibit R14.1-14.8), it was noted that the DMR allows for sterilization of the devices. I asked for the validation allowing for this process. I was provided with Test Protocol, and Test Report, Qualifying Intran Plus for a Exhibits R15.1-15.2 and R16.1-16.8).

The TP addresses functionality testing of the devices after

The TR does not reference the sterilization cycle parameters. I asked Mr. Smith for the sterilization reports that go with this TR and he replied that they could not be located.

The TR does not identify the lot number of the test devices and there was no residual testing done on these devices.

The TP and TR represent a materials/device qualification after but does not represent a sterilization validation to support the approval of a

1.F. , were originally designed with an over molded tip. In models were qualified to have the in lieu of the

). This design change was proposed to create uniformity in manufacturing for all (all models would then have a

I requested documentation on validation of the for IUP devices. I was provided with Test Protocol, IUP Functionality Test, dated and Test Report, Qualification of the Slip-on Regular Tip for Intran Plus (Exhibits R17.1-17.3 and R18.1-18.11).

Under the Purpose section of the TP it is stated, (Exhibit R17.1) The TP goes on to discuss the test method that includes a pressure test on

The TR states, . The TR reports the results of a Exhibit R18.1).

The TP and TR do not address validation of the gluing process that is used to apply the tip to the body of the catheter. The tip is glued using, which applied in a around the The gluing process is completed per SOP,

NOTE: The term is interchangeably with

I requested the original validation for the IUP x50 series. I was provided with Test Report Test, dated which states, Exhibit R20.1-20.4). This TR was completed per Exhibit R17.1-17.3).

is no longer valid because it calls for of devices. Devices are currently sterilized therefore, any validation reported in would not be relevant to current devices or processes. Again, does not make reference to the gluing process validation.

Intran Plus was originally qualified on Test Protocol, , Intran Plus Master Test Plan (Exhibit R21.1-21.14). However, that TP is not relevant to today's devices or processes, specifically because devices manufactured under this TP were and the tip was bonded using

NOTE: On 3/10/03, I specifically asked Mr. Cornwell, via email (Attachment 11.1-11.3) to provide validation for the gluing process used to bond the tip to the catheter in IUP manufacturing. On 3/11/03, I was provided with a second copy of . A list of documents requested

of and answers to questions posed to Mr. Cornwell via email is included (Attachment 11.1-11.3), as is the firm's response that was returned with our copies of requested documents on 3/11/03 (Exhibit R22.1-22.4).

In 2002, there were [illegible] complaints of catheters with electrical problems. These [illegible] complaints accounted for [illegible] devices with confirmed adhesion problems. See Observation #5.

Related Exhibits:

1.A.1. K 1.1; K 2.1; K 3.1; K 4.1-K 4.7; K 5.1-K 5.8; K 6.1; K 7.1-K 7.7; K 8.1-K 8.7; K 9.1-K 9.7; K 10.1-K 10.18; K 11.1-K 11.2; K 12.1-K 12.3; K 13.1-K 13.6; K 14.1-K 14.6; K 15.1- K 15.9; K 16.1-K 16.4; K 17.1-K 17.2; K18.1-K 18.3; K 19.1-K 19.3; K 20.1-K 20.4; K 21.1-K 21.32; K 22.1-K 22.30; K 23.1-K 23.21; K 24.1-K 24.32

1.A.2. K 2.1-K 2.4; K 25.1-K 25.4; K 26.3; K 27.1-K 27.3; K 27.4- K 7.9; K 28.1-K 28.15

1.B. K 14.1-K 14.6; K 29.1-K 29.13; K 29.10; K 29.11; K 29.4; K 30.1-K 30.6; K 31.1- K31.6; K 32.1-K 32.6; K 33.1-33.6; K 34.1-34.6; K 35.1-K 35.6; K 36.1- K 36.7; K 37.1- K 37.5

1.C.1. R9.1-9.5; R10.1-10.9

1.C.2. R11.1-11.10; R12.1-12.10; R13.1-13.10

1. D. 1. K 38.1; K 39.1 – K 39.3; K 40.1- K 40.7; K 41.9 - 41.12; K 41.1- K 41.12; K 42.1- K 42.6

1.D.2. K 38.1; K43.1- K 43. 4; K 44.1-K 44.2; K 45.1; K 46.1; K 47.1- K 47.3; K 48.1-K 48.3; K 49.1-K 49.5; K 50.1-K 50.8; K 51.1- K 51.4; K 52.1-K 52.3; K 53.1-K 53.14; K 54.1- K 54.5; K 55.1- K 55.3; K 56.1- K 56.4; K 57.1; K 58.1- K 58.3; K 59.1- K 59.3; K 60.1-K 60.5; K 61.1- K 61.5; K 62.1- K 62.11

1.E. R14.1-14.8; R15.1-15.2; R16.1-16.8

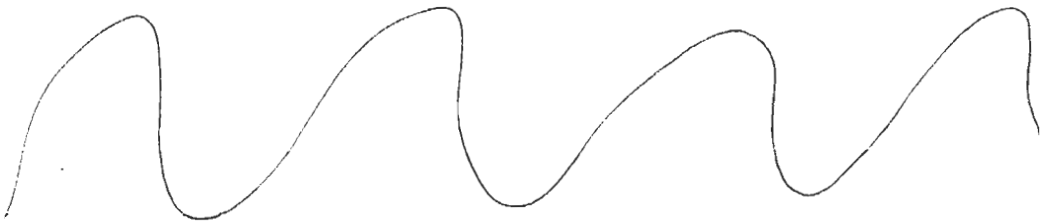
1.F. R17.1-17.3; R18.1-18.11; R19.1-19.9; R20.1-20.4; R21.1-21.14; R22.1-22.4

OBSERVATION 2

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:



Annotation: 2.

Reference: 21 CFR 820.70(i)

Observation 2 was made by Investigator Chase-Off.

Relevance:
These software systems are used to maintained many of the firm's quality systems including,

These areas of the quality system impact all devices manufactured at UTMD.

Specific software systems, including the

The software is used for the Finesse product line.

NOTE: Lack of software validation has resulted in FDA-483 Observations during the 6/01 and 3/02 establishment inspections (Attachments R13.2, Item 6 and R12.6, Item 13).

Discussion with management:
2.a.
2.b.
Mr. Smith stated that he does not understand that there is a validation requirement for the remaining systems listed in 2.b.

I told Mr. Smith that any time computer software is used to control or maintain anything required under the QSR it must be validated. Mr. Smith stated that they use a

2.c. – 2.d. These computer systems are used as a type writer not as a way to control the quality system, according to Mr. Smith.

2.e. The software used in [redacted] does not have to be validated because the process can be verified, according to Mr. Shirley.

2.f. According to Mr. Shirley, the system was instituted many years ago and they would have to see if they could find the documentation on the validation.

2.g. Mr. Shirley asked if they hadn't showed me this. I told him that he provided a Qualification of the [redacted] Final Tester (Exhibit R38.1-R38.2) but that qualification did not address the software validation. Mr. Shirley asked specifically what the software validation was lacking. I referred him to FDA's Guidance of validation of computer software to assist him in understanding what the validation was missing.

Mr. Cornwell stated that the product (IUP) has been tested on that software for at least [redacted] and that the devices work and meet specification. Mr. Cornwell stated that it is an issue of revalidating something that has already been validated many, many years ago. Mr. Cornwell did not believe that validation was applicable in this situation.

Additional details of the observation: **2.a.-g.**

SOP, [redacted], Document and Data Approval, Issue, and Control, refers to an electronic document control system, [redacted] Exhibit R23.1-23.3). This system has not been validated; however, Mr. Smith provided a [redacted] (Exhibit R24.1-24.7).

[redacted] is a software system used to manage numerous aspects of the quality system, as listed in the Observation.

Incoming raw materials are inspected according to SOP, [redacted], Receiving Inspection (Exhibit R25.1-25.5). [redacted] states that if ANSI/ASQC Z1.4 is used, then [redacted] is to be used to determine if the inspection status is [redacted] has not been validated for this function; however, Mr. Smith provided a Test Protocol for validation of this function, [redacted] (Exhibit R26.1-26.8).

Further, [redacted] is used to [redacted] (Exhibit R25.3, Section 3.11) [redacted] (Exhibit R25.3, Section 3.12.2). [redacted] has not been validated for these processes.

[redacted]

are changed then the part revisions should be updated in the maintenance screen in [illegible] has not been validated for these uses (Exhibit R27.6-27.7)

SOP, [illegible] Non-Conforming Materials, states that NCMR forms are generated through [illegible] (Exhibit R28.2, Section [illegible] Further, the SOP indicates that [illegible] is also used for generating [illegible], according to SOP, [illegible] SOP, [illegible] NCMR form also refers to form [illegible] being generated through [illegible] (Exhibit R29.2, Section [illegible]) and that [illegible] has not been validated for these uses.

Mr. Smith provided a UTMD Internal Memorandum dated [illegible] which states that because UTMD controls quality records in a [illegible] system, validation is not necessary. Further, the [illegible] system is referred to as a "reference", not the sole source of information. Finally, ongoing use of the system indicates no inadequacies in the integrity of data contained in the database. Therefore, no formal validation activities have been pursued. (Exhibit R30).

According to SOP, [illegible] Customer Complaint System, complaints are entered and maintained in the [illegible] (Exhibit R31.3, Section [illegible] SOP, [illegible], Customer Complaint Evaluation (Exhibit R32.3, Section 3.2.6) instructs that documentation of tests and inspections performed and the results of a complaint evaluation should be recorded in the [illegible] The [illegible] system has not been validated for these purposes.

The Corrective/Preventive Action procedure, [illegible], states that for quality assurance, data are to be collected from various locations including " [illegible] (Exhibit R33.3, Section [illegible] These software systems have not been validated.

[illegible] software is used to maintain the [illegible] according to SOP, [illegible], Section [illegible] (Exhibit R34.4). [illegible] has not been validated for this purpose.

Per SOP, [illegible] computer software is used to control [illegible] Exhibit R35.2-35.5). This software has not been validated for this production process. The SOP does not instruct the equipment operator to inspect the catheter to ensure that the software has correctly [illegible]

According to [illegible], Finesse II ESU2-110 and ESU2-220, Section [illegible] the units are [illegible] (Exhibit R36.16). Per Section [illegible], the [illegible] (Exhibit R36.17). On 3/6/03, during a tour of the [illegible] room, I observed [illegible] No validation for this software program was provided.

IUP catheters undergo a final test per SOP, (Exhibit R37.1-37.8). The Final Tester operates in a environment (Section 4.5). The records the final test results and lot number of the product being tested. The s further indicates which devices need to be retested (Section 5.8). ests are conducted for

Mr. Smith provided a copy of , Qualification of Final Tester, dated (Exhibit R38.1-R38.2). This TP does not address the validation.

Related Exhibits:

2.a.-g.

R23.1-23.3; R24.1-24.7; R25.1-25.5; R26.1-26.8; R27.6-27.7; R28.2; R29.2; R30; R31.3; R32.3; R33.3; R34.4; R35.2-35.5; R36.16; R37.1-37.8; R38.1-R38.2

OBSERVATION 3

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 18 Finesse complaints in and their failure codes revealed complaints coded as failure code had information describing components as . There were only 2 complaints coded as

2. Finesse complaints that had output transistors replaced stated these were random failures. Complaint letter in indicates this failure typically happens in older systems. This system was of the ' The complaint summary for received shows the unit had only been in service since 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. complaints had no evidence of complaint and service repair history reviews . And, complaints had searches of the complaint history and/or service repair history only for the complaint unit 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 [redacted]

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.

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 [redacted] The device was sent to the manufacturer of the Tungsten wire, 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, [redacted] Non-Conforming Material Reports reviewed for the Intran Plus membrane switch for the failure, [redacted] did not document the evaluation or investigation of the failure and no corrective or preventive action was initiated.

Annotation:

3.A.1. Under consideration

3.A.2. Under consideration

3.A.3. Under consideration

3.B.

3.C. Under consideration

3.D. Under consideration

Reference: 21 CFR 820.100(a)(1)

Observations 3.A.1-3. were made by Investigator Coleman.
Observations 3.B.-D. were made by Investigator Chase-Off.

Relevance:

3.A.1. CAPA system failure because procedures do not define failure codes and cannot assure they are uniformly applied.

3.A.2. CAPA system failure to detect potential recurring quality problems and there is no investigation .

3.A.3. CAPA system failure -- Inadequate review/analysis of complaint and service data in order to identify existing and potential causes of quality problems.

Observation 3.B. specifically relates to the lack of failure investigation in IUP manufacturing. More generally, UTMD does not maintain a failure investigation SOP for anything other than devices evaluated as part of a compliant investigation.

Observation 3.C. specifically relates to a Letz Loop Electrode and generally relates to the fact that UTMD's procedures for complaint handling and corrective and preventive action are inadequate.
Observation 3.D. specifically relates to a reoccurring problem with the Intran Plus membrane switch and generally relates to the inadequacy of the firm's NCMR procedure.

Discussion with management:
3.A.1. Mr. Cornwell said, point taken will look at definition and make them clearer, not significant, unit are old, low volume device, no correlation from unit to unit. In context it is not a significant issue. Engineers know what's going [on].
Mr. Shirley said its the experience of engineer reviewing.

Mr. Smith said it makes sense to him as written – [redacted]. [They are] not going to collect a lot of data on it that will help our Quality System [redacted]

3.A.2. Mr. Cornwell said he was not familiar with this.
Mr. Shirley said it was not discussed in meetings.
Mr. Smith said [redacted] failure is common, maybe typical on older devices but it could be on a younger product.
Ms. Coleman said a CAPA should have been opened.

3.A.3. Mr. Cornwell said the people doing this are skilled engineers and are familiar with the Finesse unit – may not need detail.
Mr. Shirley said a complaint evaluation is done by multiple skilled people.
Ms. Coleman: You need to review complaints and see what action was taken.

3.B. Mr. Cornwell stated that the Observation was a false statement. I reminded all present that the Observation was made in reference to our previous discussions that engineering review of failed devices is not documented and some failed devices are not evaluated.

Mr. Cornwell quoted from Section 30 of the Preamble to the QSR stating that non-conformances do not always rise to the level of a product failure. Mr. Cornwell stated that scrap levels low. Mr. Cornwell stated that things that I was referring to (in the Observation) just don't hit the radar screen from his point of view in terms of things being important.
Mr. Cornwell wanted to know why this became an Observation, stating again that the Observation is false and that the statements are not accurate.

Mr. Cornwell asked for an example to support the Observation. I told Mr. Cornwell that they have an SOP that states that if an IUP fails an in-process test, it is to be set aside for an engineering

review. I asked where was the documentation of the engineering review. Mr. Cornwell stated that if they don't have it (the documentation), then they have determined they don't need it.

I asked if there was evaluation as to why catheters failing the final test experienced the failure. Mr. Cornwell stated that it didn't matter why the devices failed the test, particularly for

Mr. Cornwell referred to the Preamble and stated that the NCMR procedure addresses when investigations need to be conducted.

I reminded Mr. Cornwell of our previous discussions during the inspection, that if UTMD wanted to base their decision not to collect quality data on historical information then that historical data needed to be documented.

Mr. Cornwell stated that historical documentation is overly burdensome and not necessary if qualified people are making decisions or if you have a small company where these things (failures) are right on the front burner and people know about them. There is no need for documentation.

3.C. Mr. Cornwell stated that he didn't get a response back from the vendor. Mr. Shirley then stated that he had a conference call with the vendor on this issue. Mr. Cornwell stated to Mr. Shirley that the response needs to be in the record. Mr. Cornwell stated that they would have to take the Observation under consideration.

3.D. I explained that there was no reference made in the NCMRs reviewed as to why an investigation was not conducted on the non-conformance.

Mr. Smith stated that the MRB decides what rises to the level of a corrective and preventive action and documents on the record if a further investigation is necessary.

Mr. Shirley agreed with Mr. Cornwell that they followed the NCMR procedure and that they (MRB) decided not to issue a corrective and preventive action (CAPA).

Mr. Smith said that the decision not to implement a CAPA was denoted on the NCMR form.

Additional details of the observation:

3.A.1. The procedures referenced in the observation above and the associated forms are attached as the following Exhibits:

Exhibit K 63.1 – K 63.5 CORRECTIVE/PREVENTIVE ACTION,

Exhibit K 64.1- K 64.3 7436 CORRECTIVE/PREVENTIVE ACTION REQUEST, Dated

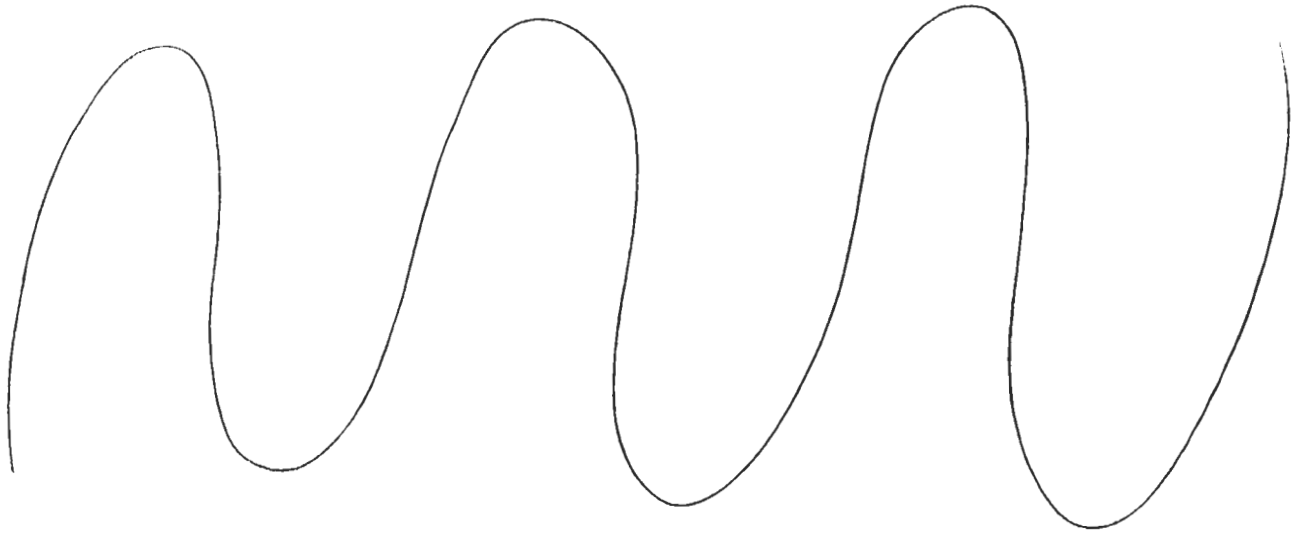
Exhibit K 65.1-K 65.9 , CUSTOMER COMPLAINT SYSTEM, Dated

Exhibit K 66.1- K 66.6 CUSTOMER COMPLAINT INVESTIGATION, Dated

Review of these procedures show they do not provide any information about failure codes, how to use them, what to do if the initial code should be changed if the investigation determines a different reason or root cause than the initial complaint. If the codes are incorrect the quality data analysis will be made using inaccurate codes that will prevent the firm from identifying existing and potential product quality problems, monitoring for trends, and opening corrective and preventive actions as needed. See the examples below:

Coded as

The following are examples from the Finesse complaints where the complaints were coded as failure code " " yet there is also a reference in the records that identified the problem as " " which has a different failure code [but the code was left



[redacted]

Coded as [redacted]

The following are the examples of complaints coded as '[redacted] and a brief description:

[redacted]

3.A.2. The complaints listed in the following table had problems with [redacted] failures and most of the complaint follow-ups reported these as ' [redacted] The complaints listed the problems in various way for example:

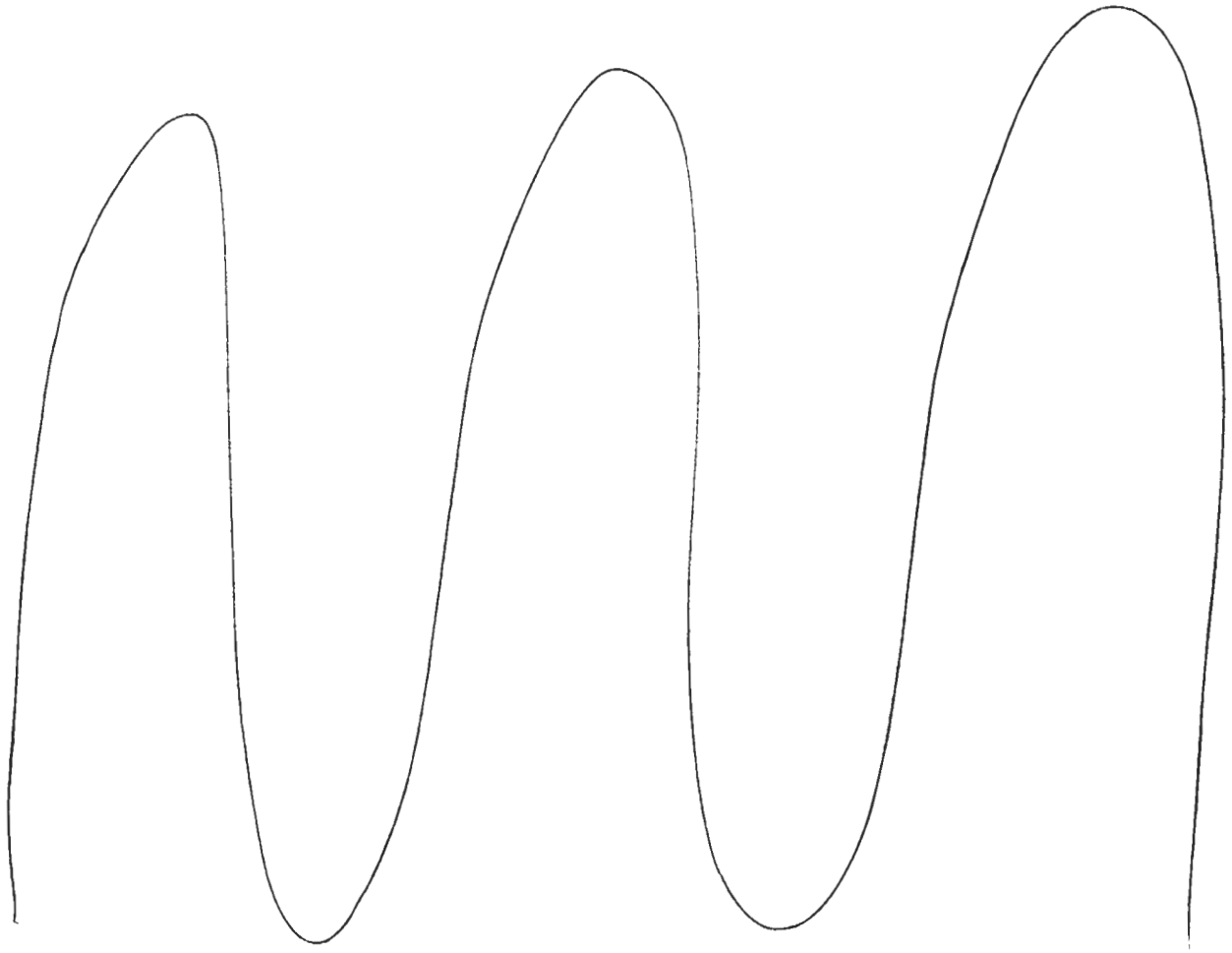
[redacted]

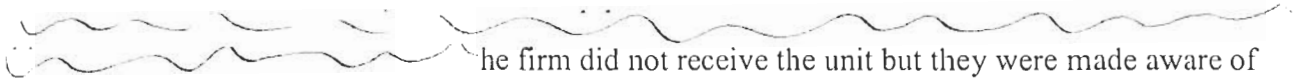
The first two complaints listed below show units that failed during the [redacted] of service. The third complaint listed is an older unit that had the same type of component failure. The firm indicates this failure is typical in [redacted]. The three complaints listed in the 483 observation all had failure code [redacted] and the fourth complaint in the table below was coded the same. The last complaint was coded as [redacted] and there is no mechanism to change it once the investigation determined the actual problem.

The last two complaints are from complaints that were collected during the inspection and are being used to show additional supporting evidence regarding the extent of the problems noted and the evaluation of this problem type. **See Exhibit K 76.1- K 76.17** which shows another example of a failure within [redacted]. There were no corrective actions opened on the component failure/s noted below.

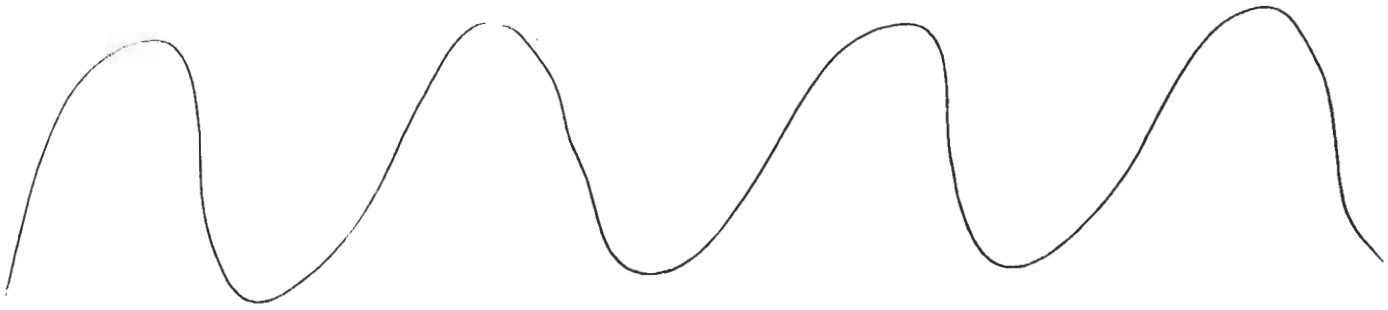
This an example of where the component data should be reviewed and evaluated. They cannot recognize potential problems because their system will not show them since component failures may only show up as

The following abbreviations are used: CC #= complaint number; Rec'd = received date; SN= serial number; Info = Information





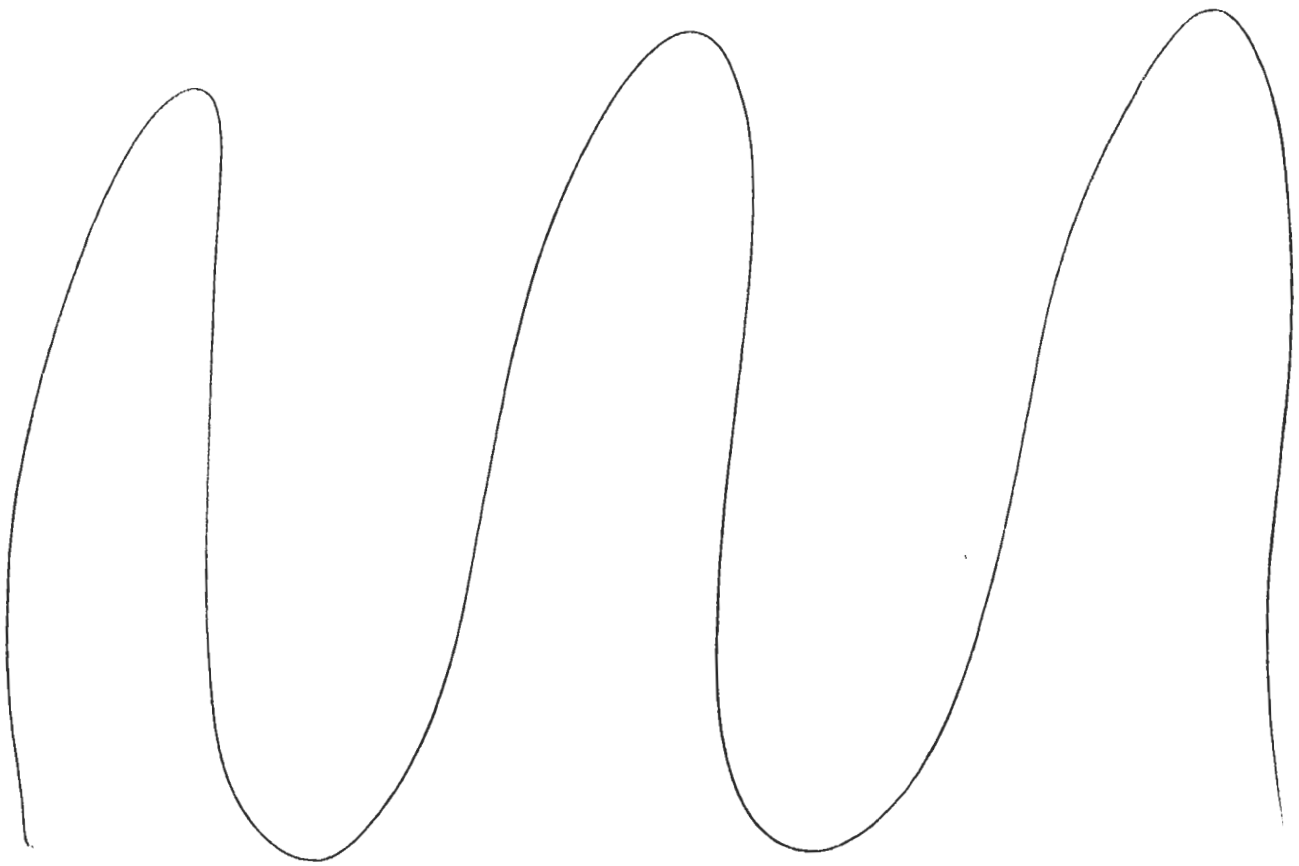
he firm did not receive the unit but they were made aware of the problem. They had enough information to do a routine follow-up and search on the complaint unit service and repair history and their complaints for similar problems. There is no indication from the information in the complaint that any other review or evaluation was made.



The firm's procedures do not provide adequate directions or guidance on what data sources [system wide complaints, or service records system wide] to review and look for similar failures overtime or for similar component failures. If the scope of the past complaint/service reviews is limited to a single unit or single units service/repair record it is not broad enough to find any other related/similar problems with that device model or similar components that may be used across various models. If component failures are noted as there will not be adequate data for a review to detect the failures.

The Table below provides the information on the six complaints and the status of the searches for complaints history and/or service and repair history searches noted in the complaint files:

Complaint #/Model/ Recd Date	Serial No.	Type of Review	Time period referenced



3.B. In-process and finished product tests are performed during [redacted] operations for IUP catheters. Devices may be accepted, rejected, reworked, or scrapped as a result of these in-process and finished product tests.

(Exhibit R39.4, Section 4.7 B). There are no procedures describing what the engineer is supposed to do with the rejected devices. There are no procedures for failure analysis of devices rejected during production and the engineers that may perform an evaluation of these products do not record their observations. Thus, quality data is not captured or evaluated, and corrective and preventive action is not considered.

Further testing is done on IUP finished products per SOP, [redacted] – Final Test (Exhibit R37.1-37.8). [redacted] tests are conducted on the Intran Plus Final Tester unit, including [redacted] Devices that fail the [redacted] tests may not be retested. Devices that fail the [redacted] test may be retested. Devices are separated into totes based on the reject reason.

There is no procedure addressing a failure analysis to determine the cause of the failed test/rejected catheters. According to the [redacted] Materials Review Board Meeting Minutes, data is collected on the total number of IUP catheters rejected for [redacted] (Exhibit R40.1-40.13). The graph does not analyze the total number of rejects for [redacted] Total number of rejects for all [redacted] tests were analyzed in the [redacted] Corrective and Preventive Action meeting (Exhibit R41.1-41.16); however, the cause of the failures was not noted.

Beyond the total number of devices that failed for each test, there are no specifics as to the cause of the device failure (i.e. was the failure due to a process, material or workmanship issue).

Per [redacted] finished catheters are inspected for a number of attributes that directly relate to the quality of the production process and finished device (Exhibit R42.1-42.42.6). For example, there should not be any [redacted] if there are, the operator is to scrap the catheter (Exhibit R42.4).

The procedure does not address determining why the void existed or noting how many catheters were rejected for that specific failure mode. A void is indicative of a workmanship problem in applying the adhesive. Corrective and preventive action cannot be addressed if the data are not collected and analyzed to determine if a workmanship problem exists. Further note that the gluing process has not been validated (See FDA-483, Observation 1.F.)

3.C. Procedures for Corrective and Preventive Action (Exhibit R33.1-33.5) and the Customer Complaint System (Exhibit R31.1-31.9) do not include all necessary instructions on closing a complaint.

Specifically, complaint [redacted] (Exhibit R99.1-99.21) was received for a [redacted] on which the [redacted] The loop was returned to the [redacted] for evaluation (Exhibit R99.20). The complaint notes that all correspondence related to the wire breaking will be filed in the vendor file (Exhibit R99.20). The complaint was then closed.

Neither the Corrective and Preventive Action procedure (Exhibit R33.1-33.5) nor, the Customer Complaint System (Exhibit R31.1-31.9) SOPs address how information maintained outside of a Complaint, such as in a vendor file, will be returned to the corrective and preventive action system for tracking and evaluation.

3.D. The Corrective and Preventive Action SOP (Exhibit R33.1-33.5) does not provide sufficient direction as to when a corrective and preventive action should be initiated for non-conforming products. Specifically, the SOP in Section 4.2 (Exhibit R33.3) states that the Materials Review Board (MRB) will meet to, "Determine for which

The Nonconforming Materials SOP (Exhibit R28.8, Section 4.11) states that the MRB is to,

Review of NCMRs for indicates that NCMRs were initiated on incoming for (Exhibit R43.1-43.6). NCMRs were collected as examples of the (Exhibits R44.1-44.3). The NCMRs indicate that the . The disposition for all of the NCMRs was to return the part to the vendor.

There is no documentation of an investigation into the failure and no corrective or preventive actions were initiated for the failures.

The is a vendor part. The last Vendor Rating and Evaluation was done in (Exhibit R46.1-46.2) for the year problems with the were noted at that time.

An internal UTMD Memo dated also indicates that there were problems with the Exhibit R46.3-46.4).

Although there have been many research and development attempts at manufacturing a new to overcome this issue, no design changes have been implemented and the vendor has not been changed. Again, no corrective and preventive action has been documented for the NCMRs opened in to address this failure mode.

Related Exhibits:

3. A. 1. K 63.1 – K 63.5; K 64.1- K 64.3; K 65.1-K 65.9; K 66.1- K 66.6; K 67. 8; K 67. 2; K 68. 4; K 68.6; K 68.7; K 69.5; K 69.8; K 70.4; K 70.7; K 72.6; K 73.17; K 73.22

3. A. 2 K 67.1- K 67.12; K 69.1- K 69.9; K 71.1 – K 71.3; K 76.1- K76.17; K 77.1- K 77.5

3.A.3. K 67. 8; K 67.9; K 68.1- K 68.8; K 69.1- K 69.9; K 70.1- K 70.8; K 71.1 – K 71.13; K 74.3; K 75.5; K 76.1- K 76.17; K 77.1- K 77.15;

3.B. R37.1-37.8; R39.1-39.6; R40.1-40.13; R41.1-41.16; R42.1-42.6

3.C. R31.1-31.9; R33.1-33.5; R99.1-99.21

3.D. R28.8; R33.1-33.5; R43.1-43.6; R44.1-44.3; R46.1-46.2

OBSERVATION 4

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

Specifically,

complaints dated were reviewed for cracking/brittle IUP catheters. The original CAPA was opened and closed 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.

This is a repeat observation from the Establishment Inspection of 4/02.

Annotation:
4.

Reference: 21 CFR 820.100(a)(3)

Observation 4 was made by Investigator Chase-Off.

Relevance:
This observation relates to IUP catheters that were in packaging prior to The request for documentation of the risk analysis and product evaluation was made during the establishment inspection as well as the current inspection.

Discussion with management:
During the inspection, I asked Mr. Smith if UTMD had documented an evaluation of patient risk and product evaluation for the brittle/cracking catheters. I reminded Mr. Smith that I had made the same request of documentation during the previous inspection. Mr. Smith stated that there was no documentation on this issue. Mr. Smith reminded me that he and Mr. Cornwell, specifically, had discussed the issues of patient risk and materials evaluation at the time the complaints started coming in; however, documentation of the risk analysis and materials evaluation was not formally made.

I asked Mr. Smith, during the inspection, if a new corrective and preventive action (CAPA) had been opened to address the continuing complaints. He stated that there has been no new CAPA, as they feel appropriate preventive and corrective actions have been taken.

At the close-out inspection Mr. Cornwell directed me to his written response to the previous FDA-483, Item 2 (Attachment R12.2). Mr. Cornwell believes that written response adequately addresses the Observation. A copy of select pages from Mr. Cornwell's response letter dated 5/9/02 are included for reference (Attachment R16.1-16.2).

Mr. Cornwell provided a Memo, dated 3/10/03, that summarizes Brittle Catheters for the years (Exhibit R47).

Mr. Cornwell stated that the FDA-483 Observation should not have been listed again. He went on to say that he was disconcerted in that, no one from FDA had telephoned him to tell him his response to the previous FDA-483 was inadequate.

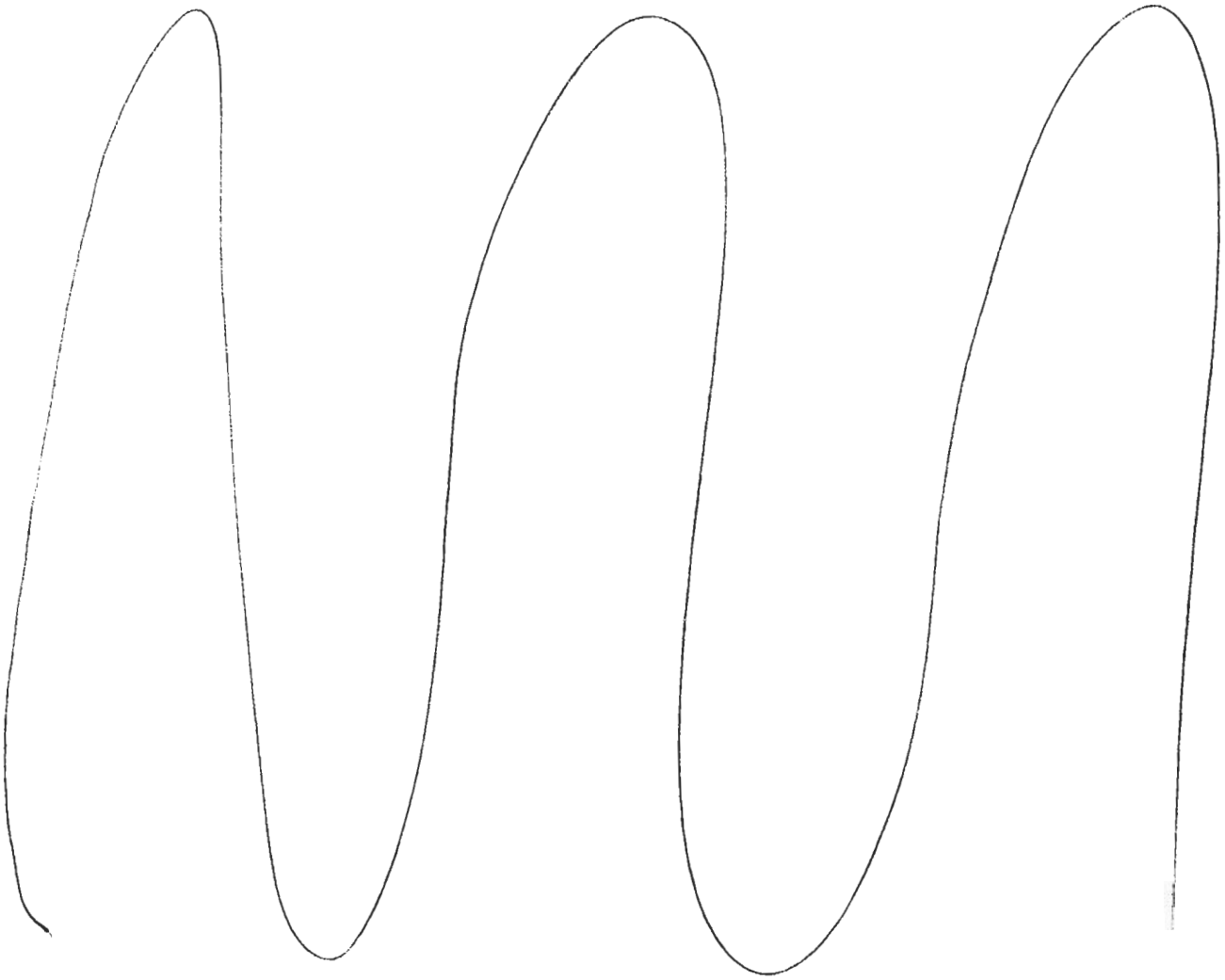
Additional details of the observation:
catheters packaged in trays have been found to be brittle and cracking. Additionally, IUP catheters that have been sterilized in trays have been found to be brittle/cracking. A combination of and exposure to light was determined to be the cause of the product defect. The original Corrective/Preventive Action Request, is included (Exhibit R45.1-45.3).

IUP catheters have a five year shelf-life; therefore, devices may be on the market until December 2005 that were and packaged in trays.

UTMD no longer any products) and changed to an opaque packaging, tray, to prevent light damage to devices in

The following complaints were reviewed during this inspection:

Complaint#	Date	Comments



Related Exhibits:

4. R45.1-45.3; R47; R48.1-48.4; R50.1-50.8; R51.1-51.7; R52.1-52.9; R53.1-53.8; R54.1-54.8; R55.1-55.9; R57.1-57.7; R58.1-58.8; R59.1-59.7; R60.1-60.8; R61.1-61.8; R62.1-62.5; R63.1-63.7; R64.1-64.11; R65.1-65.8; R66.1-66.7; R67.1-67.5; R68.1-68.15; R69.1-69.7;R70.1-70.7; R71.1-71.10; R72.1-72.7; R73.1-73.10; 74.1-74.7; R75.1-75.7; R76.1-76.6; R77.1-77.6; R78.1-78.5; R80.1-80.11; R81.1-81.7; R170.1-170.6; R171.1-171.5

OBSERVATION 5

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 [redacted] : complaints accounting for 9 devices were confirmed for adhesion problems at the IUP [redacted] 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 [redacted] gluing process, which has not been validated; therefore, there is no assurance that corrective and preventive action has been addressed in retraining.

Reference: 21 CFR 820.100(a)(4)

This Observation was made by Investigator Chase-Off.

Relevance:
This Observation relates to IUP devices.

Discussion with management:
During the inspection, I asked Mr. Smith if a corrective and preventive action had been initiated for adhesion problems at the [redacted] Mr. Smith stated that no CAPA had been opened.

During the close-out discussion, Mr. Cornwell stated that there was no CAPA required in this instance. Failures included 1 complaint on [redacted] models made, and 4 complaints on [redacted] of a different model made (Exhibit R82); therefore, the process is working as intended, according to Mr. Shirley.

Mr. Cornwell asked Mr. Smith if [redacted] had been tracking complaints since retraining on the process. Mr. Smith stated that he had no report of that tracking but that he (Mr. Smith) had spoke to [redacted] about this issue.

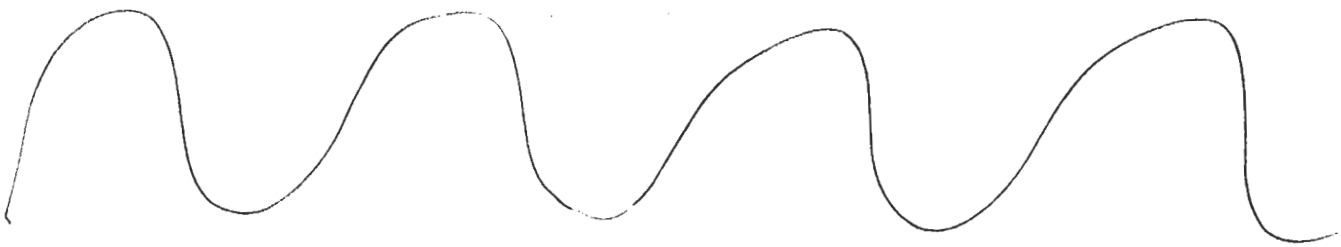
Mr. Smith stated that the testing done on returned catheters is rigorous; there may be other reasons why the device failed. The testing doesn't prove that adhesion problems are why the device failed; adhesion is just a "possibility" of why the device failed.

Mr. Cornwell stated that they believe the gluing process and [illegible] have been validated and the data show that non-conformities are relatively insignificant.

Mr. Shirley added that complaints have been decreasing every year.

Additional details of the observation:
Intrauterine pressure catheters (IUPs) of models x50 have always been manufactured with a [illegible] In [illegible]., IUP x00 models were approved for manufacture using a [illegible] as opposed to the original design of an over molded tip.

The following complaints were reviewed:



connections.

The Complaint Summary states, "No corrective action necessary." [illegible] " Exhibit R83.4

It should be noted that the Investigation Log (Exhibit R83.3) indicates that [illegible] was low and references a value of [illegible] however, the Complaint Evaluation, Evaluation Results shows that the test result was [illegible] (Exhibit R83.5-83.6). This discrepancy is not explained in the Complaint documentation.

The Complaint Summary (Exhibit R88.4) states that manufacturing, and manufacturing engineering were notified of the complaint. No other corrective or preventive action was documented.

The Complaint Summary states that manufacturing and manufacturing engineering were notified of the defect. It goes on to state that there has been a reduction in the number of defects due to updated processes was updated in and training (Exhibit R90.4). No other corrective or preventive action was documented.

The Complaint Evaluation indicated that units leaked at less then (Exhibit R91.7) All units that had insufficient adhesive application were from lot 120496. The units did not meet the specification in (Exhibit R91.8).

The Complaint Summary states that manufacturing, and manufacturing engineering were notified and that reduction in complain frequency was related to updated processes updated in and training (Exhibit R91.4). No other corrective or preventive action was documented.

The Complaint Summary states, "No corrective action required. Manufacturing engineering was notified of the defect. Training per has been completed since this unit was manufactured." (Exhibit R95.4)

Further, these complaints are all related to poor adhesive application at the The gluing process has not been validated (See FDA-483 Observations 1F and 11A and B); therefore, there is no assurance that corrective and preventive action has been adequately addressed in retraining.

Rev ✓ was the procedure used for the gluing process until all IUP procedures were changed in In into the current procedures, to Transducer (Exhibit R97.1-97.5) and

Related Exhibits:

5. R82; R83.1-83.10; R84; R85.1-85.6; R86.1-86.6; R87.1-87.8; R88.1-88.14; R89.1-89.5; 90.1-90.24; R91.1-91.11; R92.1-92.8; R93.1-93.7; R94.1-R94.6; R95.1-95.10; R96.1-96.9; R97.1-97.5

OBSERVATION 6

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 . and received, along with the device, by UTMD or

Reference: 21 CFR 803.50(a)(2)

This Observation was made by Investigator Chase-Off.

Relevance:

The Observations relate to the firm's handling and review of complaints to determine if they warrant a Medical Device Report (MDR). Specifically, the Observations relate to the Finesse electrosurgical unit and a Letz Loop Electrode.

Discussion with management:

Mr. Smith stated that the firm followed their procedure and documented that. Mr. Cornwell asked if I just disagreed with the firm's decision. I told Mr. Cornwell that I did not agree with the firm's decision; and I informed Mr. Cornwell that the Observation would be reviewed by CDRH personnel

and that the final decision regarding whether or not the items should have been MDRs will be made by CDRH.

Additional details of the observation:

6.A. A MedWatch report was filed for a Finesse Electrosurgical Generator and Smoke Evacuation System (ESU) that had the machine stop producing current in the middle of a procedure. The physician was performing a LEEP procedure and had made the top and bottom cuts in the cervix when the machine ceased functioning. The tissue could not be totally excised. The patient had to be taken to surgery to finish the procedure (Exhibit R98.5).

UTMD's Clinical Review Board (CRB) reviewed the complaint and decided the complaint was not a reportable event (Exhibit R98.2) because the surgery was completed with no adverse effects on the patient.

This event resulted in the patient requiring surgical intervention at an adjoining facility for the procedure to be completed.

This Observation and accompanying complaint, (Exhibit R98.1-98.12), should be reviewed by CDRH personnel to determine if the firm was negligent in not filing a timely MDR.

6.B. A MedWatch report was filed for a Letz Loop Electrode that broke during a LEEP procedure. The piece of broken wire was not found by the user facility. UTMD recorded this event as complaint . (Exhibit R99.1-99.21).

UTMD's Clinical Review Board (CRB) reviewed the complaint and the Materials Review Board (MRB) determined that the event was not reportable. According to UTMD procedure Customer Compliant System, Section (Exhibit R31.8), the CRB is comprised of the company president (Mr. Cornwell), the Quality Assurance Manager (Mr. Smith) and/or other designated individual, and other personnel appropriately related to the product or service. The CRB documentation is signed by Mr. Cornwell, Mr. Smith and Product Manager (Exhibit R99.3).

According to the NCMR procedure (Exhibit R28.2), the MRB is comprised of representatives from Quality Assurance, Engineering Manufacturing/Production, and Materials or Buyer/Planner Groups, and may include others as necessary.

The CRB Review, Product Evaluation states, (Exhibit R99.1) However, the MedWatch report states that the portion of the loop that broke off was not recovered by the user facility.

The CRB Review indicates that the CRB believed that the wire of the broken loop did not cause and would not have caused a serious injury (Exhibit R99.1); therefore, the event was determined not to be reportable.

The MedWatch report does not state what the patient outcome was or if the patient had to receive further treatment to complete the procedure (Exhibit R99.5). UTMD's complaint does not contain this information either (Exhibit R99.1-99.21).

The Complaint Evaluation states that the wire broke at the [illegible], and that the [illegible] was melted and charred on the right side. Neither the MedWatch report nor the complaint indicate if the device was melted while inside the patient or after removal.

LEEP procedures involve excision of cervical tissue by electrosurgical means (i.e. use of the Letz Loop Electrode). If the wire was not retrieved and the device was observed to be melted, and charred, it is possible that similar failures could result in serious injury to patients.

This Observation and accompanying complaint, [illegible] should be reviewed by CDRH personnel to determine if the firm was negligent in not filing a timely MDR.

NOTE: [illegible] additional complaints [illegible] related to loop electrodes breaking were reviewed (Exhibits R165-R167); these complaints did not contain corrective or preventive actions.

UTMD's procedure for Post Distribution Monitoring, [illegible] has been included (Exhibit R100.1-100.7).

Related Exhibits:

6.A. R98.5

6.B. R28.2; R31.8; R99.1-99.21; R100.1-100.7; R165-R167

OBSERVATION 7

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

Specifically,

A. [illegible] 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 "Note B - Spreader" "count is considered a minimum estimate due to swarming of certain colonies on the membrane"; and,

3. lacks information on testing of caps, ports, and inner lumens of devices.

B. Rev ✓ and the current Titled, Bioburden, signed by does not specify which extraction method is to be used. bioburden tests reviewed , revealed the extraction method was immersion and manual shaking, but this method has not been standardized and controlled in the procedure.

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 bacterial counts to be and,

2. it does not include a diagram of the compressed air system identifying points of use and justification for why there is only sampling point.

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

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.

E. Rev. ✓ Permanent Equipment Assembly and Servicing Guidelines states that wrist straps or ankle straps must be used for Electrostatic Discharge control (ESD), Section 7.1.5. The wrist strap system currently being used works in conjunction with a continuous monitor. The monitor has indicator lights, Only the indicator has an audible alarm to indicate a failure. and warning lights must be directly observed by the operator as they are not accompanied by an alarm should a failure occur. The procedure for use of the ESD system and continuous monitor cannot be effectively implemented in that,

1. on 2/27/03 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 light was not visible; and,

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 system lights.

F. Procedure , 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.

G. The Instrument Calibration Procedure, used by for 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 (Test Method 1 or Test Method 2).

Annotation:
7.A.1-3. Under consideration
7.B. Under consideration
7.C.
7.D. Under consideration
7.E.
7.F. Correction promised in two weeks
7.G. Under consideration

Reference: 21 CFR 820.70(c)

Observations 7A-D were made by Investigator Coleman.
Observations 7E-G were made by Investigator Chase-Off.

Relevance:

7.A.1-3. System wide to all products made that are labeled as sterile.

7.B. All sterile devices: The bioburden test method has not been specified and method being used may not be capable of providing accurate data. Firm has devices that are in contact with fluids and blood.

7.C.1-2. All devices that use extrusion molding components and all devices in contact with compressed air since only [illegible] is tested.

7.D. All extruded tubing components used to make devices.

7.E. The Observation relates to control of electrostatic discharge that can effect any device sensitive to such an environmental condition. Specifically, this would include Finesse.

7.F. The Observation relates to the firm's failure to follow their own policy.

7.G. The Observation relates to calibration of the [illegible] used in the [illegible] process for the manufacture of [illegible] tubing for construction of IUP devices.

Discussion with management:

7.A.1. Mr. Smith says – true not stated in the procedure. Reports shown to KAC to demonstrate what frequency it is being done.

Ms. Coleman – Noted and that will be in the report.

7.A.2. Mr. Smith says they will have to investigate. They are satisfied the bioburden is appropriate, they will have to check with [illegible] to provide information.

Mr. Cornwell said they will get an [illegible] on test method "we aren't the experts on this"

7.A.3. Mr. Smith says SOP tells precisely how test is performed.

Ms Coleman said the bioburden tests reviewed showed that you're doing testing but doesn't say what need to be tested [illegible]

Mr. Cornwell said they needed an expert opinion on the issue

Ms. Coleman explained that device is only checked on the out side, you have inside part of the devices that need to be examined.

7.B. Mr. Smith they use a It's not documented but it is their selection.

Ms. Coleman suggested they look at the procedure provided by the lab. It says you must select a method.

7.C.1-2. Mr. Cornwell said this has been discussed at length.

Mr. Smith said this was done pre ; it doesn't give the rest of the study that checked IUP components to show what the bioburden was on those device.

Mr. Cornwell firm's view is that we don't consider these things as causing procedures to be inadequate. Don't know why we need a diagram of the compressed air system – this is overkill and prohibitive. Air is not part of the conformance of the product … not an aseptic process using air.

Mr. Smith – Doesn't contribute to the bioburden on the product. Sterilization is an overkill …. so we don't worry about this. Bioburden on the product is in the range of … not necessary to control.

7.D. Mr. Shirley: We test product at the end for bioburden and it is fine.

Mr. Cornwell: We agree that equipment should be cleaned and pay attention to cleaning.

Mr. Smith: He doesn't know what the procedure says and doesn't know if there are filters between the upper and lower trays.

Mr. Cornwell: What affect on product? [to Mr. Smith and Mr. Shirley]

Mr. Shirley: Main issue is type of product coming out if bioburden is low its ok.

7.E. In response to my comment that the operators cannot effectively use the ESD monitoring system as it is currently being maintained (with the lights being blocked, and a monitor not being visible to the operator), Mr. Shirley stated that he disagrees and that the system can be used as is.

Further, Mr. Cornwell stated that he did not see how the Observation relates to the process and device (Finesse, assembly/manufacturing/repair), did not believe that the system even needed to be maintained, and stated that the firm does not associate ESD with environmental control.

7.F. Mr. Cornwell stated that the Observation would be corrected within

7.G. Mr. Cornwell and Mr. Shirley objected to the Observation being placed under Environmental Controls and argued that it should be placed elsewhere in the FDA-483, but that the Observation would be taken under consideration.

Additional details of the observation:

7.A.1-3. I asked Mr. Smith how they selected the products listed in the procedure for bioburden testing. He provided a memo to explain their rational for which products were selected. **See Exhibit K 84.1** memo dated Subject Product Bioburden Test Rationale.

, Rev Microbial Bioburden Testing of Devices, dated is attached as **EXHIBIT K 78.1-K 78.4**, it does not state the require frequency for submitting the devices listed for bioburden testing. The firm says they do testing on the products listed in the procedure and I reviewed examples of the bioburden testing. However, to assure this is done as required it should be included in the controlled SOP document.

See additional discussion under FDA 483 item 7 B because the bioburden test method impacts on the accuracy of the bioburden counts.

I asked Mr. Smith how they established the Alert/Action levels given in He provided a memo [See **Exhibit K85.1- K 85.8**] , Subject Bioburden limits. The report shows the analysis of bioburden data from The report states the data does not have a normal distribution. . The bioburden populations are extremely variable, often changing as a logarithmic function between samples The most complicated devices, with more components, and more manual operations, have the higher product bioburden levels.

The alert limits were set at approximately bioburden and the action limits were set at approximately bioburden. They should be re-evaluation their bioburden data on basis and comparing it with current limits for accuracy.

EXHIBIT K 78.3 and K 78. 4 for "MICROBIAL BIOBURDEN TESTING OF DEVICES" shows the Alert/Action Levels in the procedure and describes what Actions to take when they are exceeded.

It does not provide information on what to do when situations like the words "Swarming" are found in the report results in the "Note B" and some colony counts are given for the sample results.
I asked Mr. Smith to contact their lab since he did not know what swarming meant. I requested he get their explanation on the difference between swarming and TNTC and why they give colony counts on swarming results.

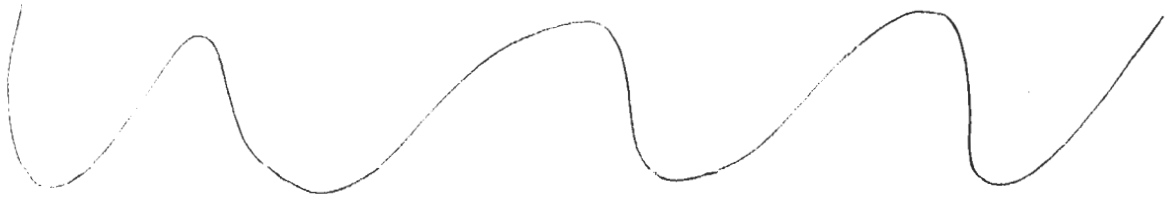
On the swarming versus TNTC questions to the lab Mr. Smith reported: [redacted]

The Note B – Spreader - on the bioburden test reports [see **Exhibit K79.4**] states: [redacted] The colony counts reported when swarming occurs are the [redacted] number of colonies that can be counted because they are seen underneath the swarming colony/ies that already covered the membrane filter surface or a plate.

Since colony counts are given the results were considered as passing because the colony counts shown are within the Action/Alert limits. But, the bioburden test results with swarming should have been treated as sample/s that failed the test because the growth of one colony is so prolific if covers the membrane or plate. The procedure should require some kind of corrective action if swarming occurs and not just accept the results as ok. The procedure also does not mention or define TNTC – Too Numerous To Count which is a common lab term that would require action due to failing results.

The following is a list of bioburden test reports I reviewed and found "swarming": [The lab reports listed below are attached as **Exhibits K 79, K 80, K 81, K 82, K 83**]

Lab Report # Device/Lot # Date



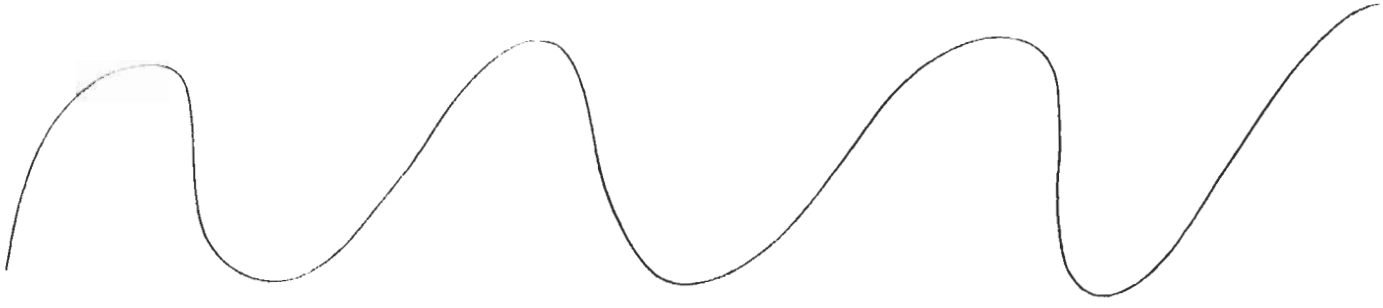
****Exhibits** for these devices include: Bioburden lab reports, work order traveler documents, Master Product BI tests report, LAL Lab Reports, and sterilization processing documents for Chambers

The procedure lacks any information to assure the caps, ports, and inner lumens of devices will be tested as needed when bioburden testing is performed. See **EXHIBIT K 78.1-K 78.4** Rev ✓ Microbial Bioburden Testing of Devices, dated

Based on the review and evaluation of this procedure and bioburden testing I found the procedure inadequate in that it did not state the required bioburden testing frequency, there were inadequate directions for dealing with situation results such as swarming colonies, and no detail as to what parts of the devices should be included for testing.

7.B. The following are examples of lab reports reviewed during the inspection for bioburden testing that shows the test method uses

Lab Report # Device/Lot # Date



The reports listed above in descending order are attached as Exhibits K79, K80, K 81, K 82, K 83, K 86, and K 22.

, Microbial Bioburden Testing of Devices, dated does not state what bioburden test method should be used. I asked Mr. Smith where their procedures specify this test method and he referred me to the SOP's from their contract laboratory. The SOP listed in the 483 text is attached as **Exhibit K 87.1- 87.31**. This current SOP was signed by Mr. Smith during My review of this SOP did not reveal where a specific bioburden test method was selected by the firm. **Exhibit K 87. 9** states under

Bioburden test reports show the method that is used by the lab but the firm should have it specified either in their internal procedures or in the contract with the lab.

Exhibit K 80.1- K 80.55 is a copy of the older lab SOP going back to This also shows the various test methods to select from but it does not show a designated bioburden test method for Utah Medical.

During the inspection I asked Mr. Smith if he knew how their devices were handled for the bioburden testing. He did not so I asked him to check with the lab to answer the question/s for me on how the devices were handled for bioburden testing. The IUP and Deltran devices have tubing and/or connectors and I wanted to know if the tubing was cut in pieces or if the inner lumens flushed. On 3/4/03 I asked Mr. Smith if he had an answer from the lab on the bioburden test method regarding the device. [did they rinse lumens, ports or cut up the tubing parts of the devices]. He told me if it says . He says experience has shown bioburden is on the outside where people handle the device and the caps/ports come right off the extruders and or injection molding equipment. This means that they are only checking the bioburden counts on the outside of the device and not what is inside the tubing, connectors, ports, and/or caps.

The components from extrusion molding are used in further processing, handling, and assembling steps during manufacturing. [For example it is tested to make sure there are no occlusions; the , and other steps.] The tubing is exposed to other operational steps after molding that could change the microbial load after molding. They have other devices with tubing, connectors, ports, and fluid pathways.

The bioburden test method is not specified and since the method being used is of the whole device the results obtained may not show the actual bioburden levels on the devices.

7.C.1. Review of , Environmental Control and Monitoring, Rev ✓ dated does not require sampling water from the extruder. [**See Exhibit K 89.1- K 89.10**] **EXHIBIT K 90.1-90.3** is a copy of the Lab Report NO. dated for Total Plate Counts on the water. There is no routine sampling of water from the extruder and cooling tray. There is no data to show what the sampling frequency should be at this point in production.

The firm provided Lab Report NO. dated for Presterilization Bioburden Counts on tubing. [See **Exhibit K 91.1- K 91.8**] They identified it as correlating data between tubing made on the extruder and what shows up on the product as bioburden. **Exhibit K 92.1** PART DESCRIPTION FOR LABORATORY NUMBER is the identification of the different parts submitted for testing. The method used for bioburden testing is So there is no assurance that it accurately reflects the bioburden on some parts. [See discussions 483 item 7. A. on the bioburden test method and 483 item 8]

The firm has not repeated this bioburden testing on tubing and there is no information to correlate it to the current production environmental conditions and bioburden levels. Plus there was a change in the tubing material in Exhibits R172.1-172.91; R173.1-173.11; R174.1-174.5; R175.1-175.4; R176.1-176.11; R177; R178.1-178.12).

7.C.2. , Environmental Control and Monitoring, Rev dated 0 in Section addresses COMPRESSED AIR SUPPLY BIOBURDEN. The firm does not have any diagram or map showing all the locations where compressed air is supplied for use in production and labs. There is no mechanism for identifying all the points of use for collecting samples. Compressed air is used in the For example, compressed air is used for a tubing in production. The procedure only requires a test at site on the cleanroom map see EXHIBIT K 89.9. The firm does not have any data to support only sampling air at this .

7.D. Review of , EXTRUSION SET-UP, Rev. Dated in section states , Extrusion Set-up. Based on the observations made in 7 D. 1,2 the firm has not been following this procedure. There is also no requirement to document the "clean" status of the equipment including the take out belt prior to use. See **Exhibit K 40.1- K 40.7**

Review of Rev. , EXTRUSION RUNNING PROCEDURE, Dated does not address any type of cleaning that would correct or prevent items noted in 7 D. 1,2,3, and 4. See **Exhibit K 41.1- K 41.12**

Review of Rev. , EXTRUSION CLEANING PROCEDURE, Dated revealed section SHUT DOWN OF OTHER EQUIPMENT at directs the water to be drained from the Sizer and the reservoir should be emptied. But, it does not address any actual cleaning or inspections. See **Exhibit 42.1- K 42.6**

The firm's failure to follow their own cleaning procedures increases the risk of exposing the tubing to higher bioburden levels from the recirculated water in the extruder. This recirculated water is in contact with unclean surfaces as observed and noted above in 7 D. In addition they have taped an empty cleaning bottle on the water control float which cannot be easily cleaned. They have not retested the water at the extruder since the original testing in The firm their water for extrusion and hand washing now but it should routinely be tested at the extruder and cooling tray because of the potential for microbial growth in this process.

The take off conveyer belt should be routinely checked to assure it is clean, does not have surface abrasions and/or cracks, or other foreign matter that can harbor bacteria.

The firm should have written procedures covering routine microbial checks of the water used in extrusion, water from the extruder, and product contact surfaces evaluated for microbial levels and evaluate the results for controlling environmental conditions in, on, and around the extrusion operations. Cleaning of the conveyer belt and other areas noted in this observation should be on a documented routine cleaning schedule.

7.E. Electrostatic discharge (ESD) protection is required by procedure , Rev. Section (Exhibit R101.1-101.12). Further, ESD protection is required by procedures, , ESU Service Procedure (Exhibit R102.1-102.11) and (Exhibit R103.1-103.11).

The ESD system was observed on 2/24/03, 2/27/03 and 3/6/03 during visits to the room where Finesse and Liberty devices are manufactured/assembled/tested.

It was observed that the ESD system includes the use of ESD protective mats at work stations, wrist straps and Workstation Monitors that continually monitor the efficacy of the mats and straps.

A Technical Brief for the Wrist Strap for Static Protection was collected (Exhibit R104.1-104.2), as were the Instructions for use of the (Exhibit R105.1-105.13).

The Instructions for the state that the wrist strap and connecting cord are working properly if the green OK light is lit (Exhibit R105.2). If the resistance is greater than ohms, then the green light goes out and the red Operator light is lit and the buzzer sounds (Exhibit R105.2).

Should an event occur in which one of the current limiting resistors is bypassed, the yellow L operator lamp slowly flashes (Exhibit R105.2). No alarm buzzes.

The Monitor is also used to monitor the status of the ESD protective mats. In the event that the resistance of the path exceeds ohms, the Mat lamp is lit; however, the audible alarm does not sound (Exhibit R105.2).

The Instruction manual, Section Installation with work surface monitoring states, (Exhibit R105.5)

On 2/27/03, the ESD continuous monitor at work station in the room was in use but the monitor was blocked and not visible to the operator. On 3/6/03, the Mat light, at the same station was blocked by a parts storage box.

On 3/6/03, the continuous monitor at station located behind station was observed to be mounted below the work station table. The monitor was mounted so far back on the work station table that I had to squat to see the monitor. The monitor was not mounted so as to be visible to an operator standing or sitting at the work station.

7.F. UTMD's procedure, ~~ Permanent Equipment Assembly requires qualification of the ESD system at or near the work station (Exhibit R101.10). No qualification documentation was observed at or near any work station in the ✓ room.

During a tour of the ✓ room, I asked Mr. Smith if there were records of daily inspection of wrist straps or operation of the equipment? Mr. Smith later told me that the procedure did not require inspection of the system. No qualification was provided for the ESD system, other than calibration records/PM (Exhibits R106.1-106.3). The PM records are not maintained in the ✓ room. According to UTMD's procedure for Preventative and Unscheduled Maintenance (Exhibit R125.1-125.3), PM records are maintained in the equipment file by the administrator.

7.G. The laser micrometer used on the extrusion molding line is calibrated by a contracting firm, ~~ I requested a copy of the procedure used for calibration. Mr. Smith provided ~~ ✓ (Exhibit R107.1-107.4).

The SOP, ~~ clearly states that there are ✓ methods of calibration, ~~
The Certificate of Calibration is incomplete in that it does not indicate which method of calibration is used on the equipment (Exhibit R132.1-132.2).

Related Exhibits:

7. A.1.-3. K 78.1-K 78.4; K79.4; K 80; K 81; K 82; K83; K 84.1; K 85.1- K 85.8

7.B. K 22; K 79; K 80; K 81; K 82; K 83; K 86; K 87.1- K 87.31; K 87. 9

7.C.1. K 89.1- K 89.10; K 90.1- K 90.3; K 91.1- K 91.8; K 92.1;

7.C.2. K 89.9

7.D.1.-4. K 40.1- K 40.7; K 41.1- K 41.12; K42.1- K 42.6

7.E. R101.1-101.12; R102.1-102.11; R103.1-103.11; R104.1-104.2; R105.1-105.13

7.F. R101.10; R106.1-106.3; R125.1-125.3

7.G. R107.1-107.4; R132.1-132.2

OBSERVATION 8

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 3/5/03, no blueprints or diagrams were available on the water system showing: piping throughout the firm, valve locations, points of use, sampling points, [illegible] mixing hookups, the [illegible] water storage tank, no incoming water specification, and no extrusion water quality specifications.
2. There are no [illegible] specifications and no mixing records for [illegible]. water.

3. [illegible] Rev [illegible] dated [illegible] for Acceptability of Handwashing Water and [illegible], Rev [illegible] dated [illegible] Acceptability of Handwashing Water show water samples were only collected from [illegible] The test procedure is inadequate in that, there are [illegible] locations for cleanroom handwashing basins and only [illegible] were sampled.

Annotation:
1-3. Under consideration

Reference: 21 CFR 820.70(a)

This Observation was made by Investigator Coleman.

Relevance:
System wide for all devices made in the cleanrooms. Firm has failed to establish adequate process control and monitoring procedures for water used in production.

Discussion with management:
Mr. Shirley: Why do they have to have a diagram.

Mr. Cornwell Doesn't see why they have to have it [diagram or blueprint]. Water is not part of process controls. They don't consider the water as being part of the product meeting conformity. Water is not part of the process as described here. [There is] no requirement to have this stuff. Do all companies have water systems done?

Ms. Coleman: Yes, many firms do have their water systems done.

Ms. Chase-Off stated there was a Guidance document for validation on the FDA site.

Mr. Smith: They have a standard for environmental monitoring of ~~~ levels and [we] have documents that [show] they have less bacteria in the water when ~~~

Ms. Coleman: They only looked at ~point for ~~~

Mr. Smith: [They can do a] comparison of putting ~~~ strip next to sample in bioburden study [they] rotate past [the] sinks on regular basis.

Mr. Cornwell: Say's this is over burdensome to have written specification on water system. He asked Mr. Smith if there was any problem.

Mr. Smith said: They have a low bioburden so [they don't need it.]

Mr. Cornwell: The proof is in the pudding.

Additional details of the observation:

The firm uses water in extrusion production for ~~~ see discussion under FDA 483 item 7 A, B, C, and D] and for employee hand washing prior to entering the cleanrooms. Water used in production and for hand washing should have the appropriate process controls and procedures to assure that its use will not interfere with or cause the finished device to fail specifications.

Mr. Smith confirmed they use ~ water in the firm and they add additional ~~~ for water used for the clean room hand wash stations and the extruder. I asked for a diagram of the water system piping to review. I was told they did not have one.

The firm should have diagrams of the water piping throughout the facility. The diagram/s should show where the ~ water comes into the building, location of all valves, connections where the ~~~ water is added, storage tank/s should identified, all water distribution lines for the different systems ~~~ should be identified, and all points of use should be numbered and identified to facilitate the sample identification. There should be reviews of the diagrams to assure there are no cross connections with non-potable water lines and that there are adequate backflow prevention devices on the system. They cannot adequately control the system if they do not have diagrams showing the system, points of use, and some identification of the sampling point/s.

I asked to see test results on the incoming water. They have not conducted this type of testing. The firm should have routine testing on the incoming water over time to determine it routinely meets chemical and microbial specifications. They also need to determine if there are seasonal variations in their area that would affect the decisions on chlorinating water for use in-house.

I asked for the firm's water specification I was referred to procedure ENVIRONMENTAL CONTROL AND MONITORING, Rev [**See Exhibit K 89.1-K 89.10**] Section has the testing as well as the wash basin specification listed as Section water specification states

I verified they are performing hand basin checks by reviewing test data from the past months. They rotate the sample locations around the production hand wash areas.

But within the areas there are hand wash stations and more in molding. None of the locations are numbered. Exhibit K 93.1- K 93.6 shows examples of the Environmental Test Results. The chlorine concentration test result is located at the bottom left of the forms. [Note: on they did not record the test results]

Mr. Smith said they did a formal study when they started their water. See **Exhibit K 94.1- K 94.2** for the protocol and **Exhibit K 95.1- K 95.2** for the results. He said they compared the results of the work in it with the Lab Report NO. dated [see **Exhibit K 96.1- K 96.5**] . Note the: Hand wash water study was done in and compared with a test.

I reviewed the study to see if it provided justification for the sampling frequency and sampling locations. This study is not adequate because they only sampled hand wash basin a This means only out of the hand wash basins were sampled in the initial study. This study did not provide enough data to justify their sampling frequency and sampling location.

The data they have from their testing reports that I reviewed cannot be evaluated over a period of time because the sampling locations are only by They should have been sampling all hand wash basins each day of use for several weeks to assure the results will be representative of each sampling point. Then after a review and evaluation of the test data then they can decide which points to sample on a rotating basis.

Mr. Smith said they do not have a wash basin diagram identifying the different basins in each dressing area. Even though the workers collecting the sample rotated to the different areas each they are still only sampling water from hand wash station out of

On 3/5/03 Investigator Coleman and Investigator Chase-Off observed the area where they [illegible] with the water and saw a [illegible] Mr. Smith and Mr. Ben Shirley were not able to trace or identify the piping and tubing observed in the area and none of it was identified. There was a black tube connected to one section of piping that went into the [illegible] barrel/drum. There was a jug of [illegible] sitting near the [illegible] There was a piece of clear tubing that came out of the drum and there was red tubing connected to another section of piping along the wall and the other end of it was directly on the floor. There was an unlabeled [illegible] gallon storage tank that was identified to us as containing [illegible] I asked if there were any records for kept for [illegible] I was told "NO" by Mr. Shirley there were no [illegible] records.

I asked to see the specification for the [illegible] they were using. [illegible] They do not have a written approved specification for the [illegible] I requested a copy of the purchase invoice. It is from [illegible]. The copy is attached as **Exhibit K 97.1**. The firm is using [illegible] to lower the microbial levels in their water. The [illegible], should have a written approved specification just like other raw materials purchased by the firm. If they do not get the right concentration then what they mix will not have the correct specification for use. They should have a written procedure for mixing [illegible] and be keeping the mix records and testing to confirm mix concentration.

Related Exhibits:

8.1.-4. K 89.1- K 89.10; K 93.1 – K 93.6; K 94.1- K 94.2; K 95.1- K 95.2; K 96.1- K 96.5.; K 97.1

OBSERVATION 9

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

Specifically,

The Qualification of the [illegible] Final Tester [illegible] dated [illegible]

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 [illegible] defects, an attribute that the tester is currently being used to evaluate.

Reference: 21 CFR 820.72(a)

This Observation was made by Investigator Chase-Off.

Relevance:
The Final Tester is used to [redacted] manufactured by UTMD. UTMD distributes approximately [redacted] catheters [redacted]

Discussion with management:
Mr. Cornwell stated that testing the equipment using devices with known defects was not a big point in the Observation.

I explained that IQ/OQ/PQ was necessary on the test equipment, that the Qualification was provided but, that the Test Protocol did not contain all necessary data.

Mr. Shirley stated that the equipment tests for electrical, a specification that is "obvious" to the engineers, including himself, that performed the qualification.

Mr. Shirley further stated that it is "obvious" that the specific items listed in the Observation are being tested for and that tests are functioning as intended.

Mr. Smith stated that when you use a piece of equipment for [redacted] and you have known defects, and you're finding known defects during this time, then you know if the equipment is working. I did not ask Mr. Smith how he knew that there were device defects if he was relying on the test equipment to determine that.

Mr. Cornwell stated that I provided no evidence that the equipment is not suitable for its intended purpose and that the Observation was "way out of line", based on a decade of use with this equipment.

Additional details of the observation:
The [redacted] inal Tester is a [redacted]
[redacted] Exhibit R37.1-37.8).

[redacted]

I requested documentation on the validation of the software that operates the final tester. I was provided with Test Protocol, [illegible] (Exhibit R38.1-R38.2).

In reviewing the TP for software validation, it was noted that the TP describes testing for: [illegible]

The TP does not indicate that devices with "known" defects were used to assure that correct test results (rejects) were detected by the test fixture.

The TP calls for a comparison of readings between each of the [illegible] test stations. However, the TP does not state what the acceptable standard deviation of those values should be.

The TP does not address any test for [illegible] The TP does not define what is meant by [illegible].

The TP and resulting data do not adequately qualify the test fixture or, validate the testing process or test fixture software to be used for finished product release.

Related Exhibits:

9. R14.1-14.8; R37.1-37.8; R38.1-R38.2

OBSERVATION 10

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

Specifically,

[illegible]

Annotation:
1. Under consideration
2.

Reference: 21 CFR 820.184(d)

This Observation was made by Investigator Chase-Off.

Relevance:
This Observation relates directly to the [redacted] device in the complaint, but also to the complaint handling system and the review of complaints by the Quality Manager. The Observation regarding the [redacted] test relates to all models of the IUP devices that do not contain [redacted] and were manufactured between [redacted]

Discussion with management:
10.1 Observation 10.1 was discussed with Mr. Smith during the inspection on 3/6/03. Mr. Smith stated that he believed that the Complaint Evaluation contained a typo. During the close-out meeting, Mr. Smith told Mr. Cornwell that he would speak to the engineer to determine if the record reflected a typo.

Mr. Shirley stated that I should have brought this Observation up at a daily close-out meeting such that a minor issue like this could be resolved.

Mr. Cornwell then informed me that Observations based on typographical errors were not helpful.

NOTE: The testing of this device was done [redacted]

10.2 At the close-out meeting, Mr. Cornwell asked Mr. Shirley if the operators were doing this test to check for [redacted] Mr. Shirley replied, "yes". Mr. Cornwell stated that you either have it or you don't [redacted] and the issue is whether you have an "open".

According to Mr. Cornwell, the check of the [redacted] hat is the acceptance activity. This (the test referenced in the Observation) is just part of the assembly process so, it is not an acceptance activity. The operator just keeps working on the devices until they get them assembled properly.

NOTE: Mr. Cornwell referred to the sensitivity of installing the [redacted] and that this test [redacted] just verifies that process before the device

moves down stream. However, this particular test, on this Deviation and Waiver is performed on devices that do not contain a

A device failing the test may be reworked, having the repaired. The rework does not involve the. Mr. Cornwell's reference to the check of the Further, the Final Tester used as the final acceptance test for the finished IUP devices does not check for ; it checks for

Mr. Cornwell stated that this was just a test for continuity, and that the reading would be . Mr. Shirley agreed with Mr. Cornwell that the reading would be

Mr. Shirley stated that this test is definitely not an acceptance activity and Mr. Cornwell agreed. Mr. Shirley stated that UTMD procedure does not identify this test as an acceptance activity.

Additional details of the observation:

10.1 Complaint was received (Exhibit R108.1-108.9). The complainant reported a burning sensation while using a The unit, lot number was returned to UTMD for evaluation (Exhibit R108.5).

Engineer performed the testing on the unit and signed off on the complaint evaluation (Exhibit R108.5). As indicated on the evaluation form, The specification for each is The test readings recorded in the record readings were outside of specifications; however, the Comments section of the evaluation states, (Exhibit R108.5)

On Mr. John R. Smith, Quality Manager reviewed and approved closure of the complaint.

The unit was returned on (Exhibit R108.6). NCMR number is associated with this RGA. The NCMR indicates that the unit was refurbished and returned to marketing stock (Exhibit R109).

The records do not indicate how the out of specification results were addressed; therefore there is no assurance that the unit returned to marketing stock met the requirements of the DMR.

10.2 On 3/4/03 Investigator Coleman and I were provided with a tour of IUP manufacturing operations in . During the tour we noted that DHRs for in-process devices contained a (Exhibit R110).

We also witnessed a manufacturing operator performing a test on IUP devices that did not contain The operator was checking the of the wires. We observed the operator perform testing on several devices. We witnessed device that gave readings and was rejected.

A review of the revealed that the did not indicate what the acceptance criteria were for the manual check of using the (Exhibit R110). It is possible to obtain positive, negative or no reading for The does not state what the operator should be looking for in accepting or rejecting the subassembly.

(Exhibit R110)

SOP, (Exhibit R111.1-111.9), which is referenced in the , was reviewed.

The procedure relies on the fixture to determine if the subassembly meets specification. The procedure does not state what the acceptance criteria is.

Both the tests on the and those to be conducted on the test fixture represent acceptance activities.

DHRs were collected to demonstrate that IUP catheters containing the were manufactured according to this Those lots collected include:

[redacted](Exhibits R112.1-112.14; R113.1-113.13; 114.1-114.13).

Related Exhibits:

10.1 R108.1-108.9; R109

10.2 R110; R111.1-111.9; R112.1-112.14; R113.1-113.13; 114.1-114.13

OBSERVATION 11

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] does not define what the acceptable [redacted] reading should be for the functionality test, rather the measured values are 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.

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

1. which lots of finished product will be used in the qualification; or,
2. what the acceptable [redacted] 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.

Annotation

11.A. Under consideration

11.B. Under consideration

Reference: 21 CFR 820.30(f)

This Observation was made by Investigator Chase-Off.

Relevance:

This Observation relates directly to the IUP devices manufactured with the [redacted], which is currently all models of IUPs.

Discussion with management:
Mr. Cornwell stated that the firm would take the Observation under consideration after reviewing the referenced documentation.

Additional details of the observation:
The Test Protocol, [redacted] does not adequately define the acceptance criteria for the [redacted] readings to be obtained during the functionality tests. The TP allows for individual device measurements to be compared to one another, but does not state what an acceptable value would be for anyone device.

Test Report, [redacted], based on [redacted] reports summary data for the functionality test (Exhibit R18.1-18.11). The summary data reports a maximum [redacted] increase in [redacted] The summary table does not report what the actual test values were in [redacted] and does not state what the maximum [redacted] decrease was, although the specification was [redacted]

Further, the TR does not indicated the lot of product that was used in the test.

Related Exhibits:
11. R18.1-18.11

OBSERVATION 12

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.

Annotation:
12. Under consideration

Reference: 21 CFR 820.30(g)

This Observation was made by Investigator Chase-Off.

Relevance:
Real time shelf life testing has not been conducted to support accelerated aging tests for any of the devices UTMD manufactures.

Discussion with management:
I explained the difference between a packaging qualification and shelf life studies on devices. I further explained that the devices must be demonstrated to withstand the time indicated by the expiration date, in this instance five years. I also explained that accelerated aging is an accepted practice to bring a device to market but, that it is expected that the accelerated aging studies will be supported by real time shelf life studies.

I directed Mr. Cornwell to FDA's website and guidance documents on shelf life studies for medical devices.

Mr. Cornwell stated that he felt that the Observation was overly broad.

Additional details of the observation:
I requested documentation to support the [redacted] expiration date on IUP devices. Mr. Smith provided Test Protocol, [redacted] Real Time Packaging Integrity Test. However, the TP, which intended for use on all UTMD devices, does not address shelf life studies on the device, rather it is a packaging qualification protocol.

Test Report [redacted] was written to document the results of [redacted] on devices packaged in [redacted] pouches, such as [redacted] umbilicath devices. Again, the TR reflects a packaging qualification, not real time shelf life studies for the devices. The Gesco umbilicath has a five year expiration date as is indicated on its labeling (Exhibits R11.4/11.9, R12.4/12.9 and R13.4/13.9)

Related Exhibits:
12. R11.4/11.9; R12.4/12.9;R13.4/13.9

OBSERVATION 13

Procedures were not established for the validation or verification of design changes before their implementation.

Specifically,

Annotation:
1.-2. Under consideration

Reference: 21 CFR 820.30(i)

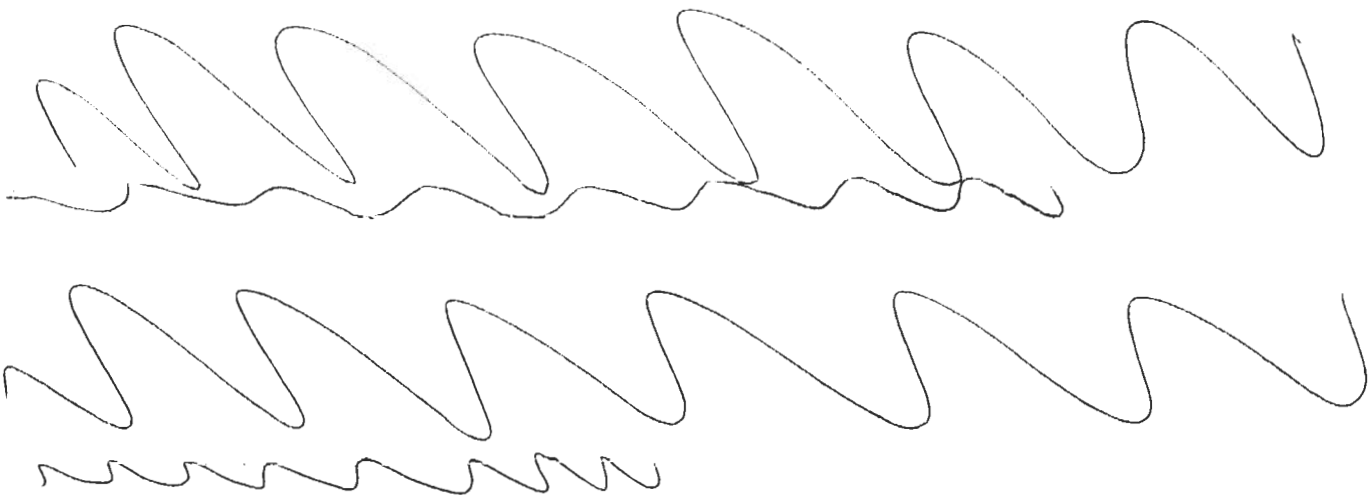
This Observation was made by Investigator Chase-Off.

Relevance:
The Test Protocol and Test Report referenced relate directly to IUP catheters. UTMD manufactures approximately [redacted] catheters [redacted]

Discussion with management:
Mr. Cornwell commented that he didn't remember this specific Observation being brought up at a daily close-out meeting. I told Mr. Cornwell that I did express concerns to Mr. Smith about leaking and adhesion problems with IUP catheters and had asked Mr. Smith if there was a Corrective and Preventive Action open regarding adhesion complaints (See Observation 5).

Mr. Shirley commented that he would like the Observation to reflect the actual number of documents that I reviewed to put this Observation into context. I told Mr. Shirley that the number of documents reviewed is not applicable in this instance but that his comment would be so noted.

Additional details of the observation: 13.1.-2.



Related Exhibits:
13.1-13.2 R17.1-17.3; R18.1-18.11

OBSERVATION 14

The design was not validated using production units under actual or simulated use conditions.

Specifically,

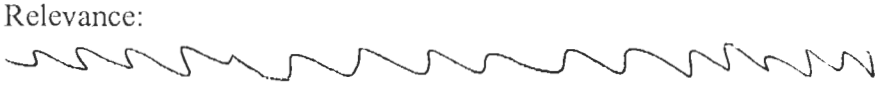
Test Protocol, [redacted], Rev [redacted] and [redacted] Rev [redacted] Qualification of a[redacted] do not evaluate shipping stresses on the new packaging after accelerated aging.

Annotation: Under consideration

Reference: 21 CFR 820.30(g)

This Observation was made by Investigator Chase-Off.

Relevance:

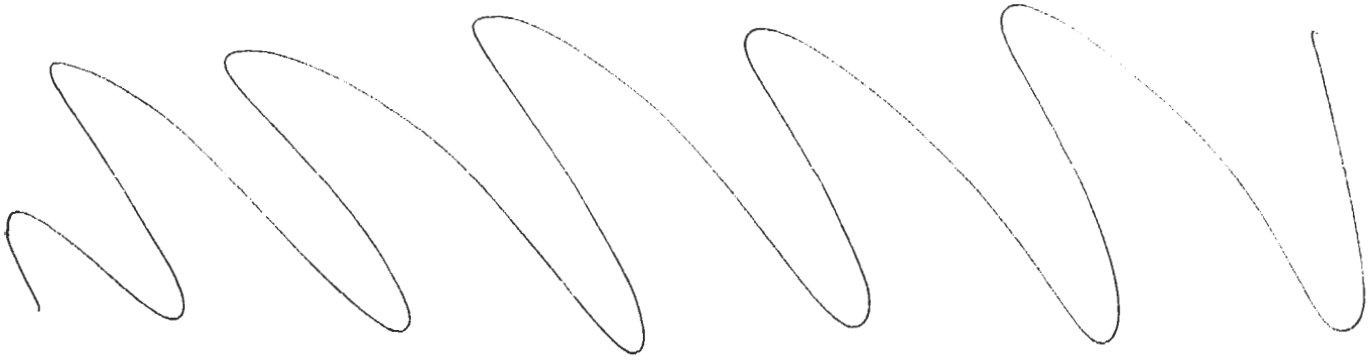


Discussion with management:
I referred Mr. Cornwell and Messrs. Shirley and Smith to FDA's website for guidance documents that could assist them in understanding the principles of packaging qualification. I further told them

that if they had trouble locating applicable guidance documents to contact me and I would provide further assistance.

Mr. Cornwell stated that they would have to look into the details of the Observation before commenting on it further.

Additional details of the observation:



Post-inspectional review of the TP revealed that the TP calls for shipping test to be performed on trays that have been [redacted] However, the TP does not state how many times the trays were [redacted] sterilized prior to the shipping tests being performed. [redacted] (Exhibit R14.1-14.8).

Related Exhibits:

14. R14.1-14.8; R115.1-115.9; R116.1-116.14

OBSERVATION 15

Appropriate design, construction, placement, and installation of manufacturing equipment have not been ensured.

Specifically,

On 3/4/03, 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 [redacted] laser micrometer, 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 [redacted]

Annotation:
15.

Reference: 21 CFR 820.70(g)

This Observation was made by Investigator Coleman.

Relevance:
All extruded components are made on this equipment with inappropriate contact materials.

Discussion with management:
Mr. Cornwell: Relates to former extruder comments.
Ms. Coleman: This is more information on the extruder.
Mr. Cornwell: Where can I get information on what "appropriate" means?
Ms. Coleman: [I or we] would expect a contact surface that can be easily cleaned.
Mr. Shirley: Tape around the back of the extruder nozzle has been there for ' ' How does tubing effect product? ... That is fine there is black ink rubbing off.—so
Mr. Cornwell These opinions are helpful and need to be taken under consideration.

Additional details of the observation:
Tape is not an appropriate contact surface on this type of equipment is production because it cannot be easily cleaned. Mr. Shirley said the tape was there because of the . The firm could have a plastic or metal splash plate made to fit this space that could be easily removed and cleaned.

The plastic tubing observed at the lead-in side of the laser micrometer was taped on and appeared to be sagging with the extruded tubing passing over and in direct contact with it. There is also black ink on it from the printing on the tubing. The laser micrometer is used to measure the tubing for correct sizing of the tubing. The tubing has to be running in the correct area for an accurate laser measurement.

The firm has attached extensions to make the side guards higher where tubing exits the cutter onto the take-off conveyor belt. These clear extensions are attached with tape. Tape is not an appropriate contact surface on product contact surfaces and cannot be easily cleaned.

OBSERVATION 16

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 laser micrometer 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.

B. The schedule for preventative maintenance of the 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.

C. The schedule for preventative maintenance of the Static Control Mats used in Electrosurgical Unit (Finesse) and Liberty manufacturing in the room:

1. is not specific as to the areas of the mats that are calibrated;
2. which specific mats are tested on each PM;
3. does not define that a surface inspection of the mat should be conducted; although, mats observed in the room on 2/24/03 and 3/6/03 were found to have burns, nicks, cuts and holes in the ESD mat surface; and,
4. PM work order dated does not indicate that the PM was completed although the work order was signed and closed by.

D. Procedure Rev. dated , Section requires tacky mats located at various room entrances to be changed On 2/24/03 and 3/6/03 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 whenever necessary as required by the procedure.

E. was not completed for the first of in the room, per SOP , Housekeeping.

Annotation:
16.A.
16.B. Under consideration
16.C.1-4. Under consideration
16.D.
16.E. Corrected, but not verified

Observation 16 was made by Investigator Chase-Off.
Reference: 21 CFR 820.70(g)(1)

Relevance:
This Observation relates specifically to IUP devices and Finesse and Liberty devices made in the room. Preventative maintenance records generally are not specific enough to determine what exactly was done to the equipment.

Discussion with management:
16.A. At the close-out meeting, Mr. Shirley disagreed that preventative maintenance is necessary for the laser micrometer just because the Instruction Manual calls for it. Mr. Shirley stated that laser

mike is not a necessary piece of measuring equipment and does not represent an acceptance activity because the firm's personnel hand measure samples during in-process inspection with a calibrated device. Mr. Shirley referred to the laser mike as a set up guide. Mr. Shirley told me that he could take the laser mike out and it wouldn't effect the quality of the product.

Mr. Cornwell stated that the PM is not required to ensure the finished device meets specification.

NOTE: Extrusion is a process such that the diameter of the tubing can fluctuate if the equipment is not operating properly. Samples measured at a specific location may or may not be an adequate representation of the diameter of the entire lot. The micrometer takes continuous measurement. It should also be noted that there is no process validation for extrusion molding (See Observation 1.D.). Finally, it should be noted that the firm's procedure, [redacted] identifies the [redacted] as a required piece of equipment for Extrusion Set-up (K40.1-40.7).

16.B. Mr. Shirley stated that he would have to review the PM and the Operations manual for the equipment.

16.C. Mr. Shirley and Mr. Cornwell objected to the Observation stating that there is not a requirement specifying what kind of written documentation is required and to what degree of detail. The individual [redacted] identified by initials on the PM was identified by Mr. Shirley as [redacted]

Mr. Cornwell stated that documentation lacking as described in Observation 16.C.1-4, is not necessary to ensure that devices conform to specifications. Mr. Shirley agreed that that the PM was not necessary to ensure that any device specifications were met.

NOTE: Finesse units that are manufactured in the [redacted] room are sensitive to electrostatic discharge (ESD) and are required by the [redacted] (Exhibit R36.1-36.23) to be manufactured in such a way as to reduce damage to components from ESD. This includes the use of ESD mats and wrist bands.

UTMD's own procedures require the use of ESD protection equipment, including SOP [redacted] Permanent Equipment Assembly and Servicing Guidelines (Exhibit R101.1-101.12), SOP [redacted] Exhibit R102.3), and SOP [redacted] (Exhibit R103.2). Therefore, it can be concluded that by not using properly functioning ESD systems in manufacturing, as required by the SOPs, damage may be done to devices, leading them not to conform to specifications.

16.D. During the close-out inspection Mr. Smith and Mr. Shirley stated that the firm's procedure does not require that the changing of tacky mats be documented. Mr. Cornwell stated that this should not be an Observation on the FDA-483.

NOTE: UTMD's procedure, I[illegible] Housekeeping, states that tacky mats are to be changed by Housekeeping personnel and that activities performed by Housekeeping personnel are to be documented on ' [illegible] logs, Sections [illegible] (Exhibits R117.5-117.6; 117.4), this includes changing the tacky mats [illegible]

16.E. I pointed out the deficiency in the log to Mr. Smith and Mr. Shirley during a tour of the [illegible] room on 2/24/03. Through the duration of the inspection, the cleaning log was completed.

Additional details of the observation:

16.A. The ' [illegible] laser micrometer (mike) is used to measure the diameter of extruded [illegible] tubing used to manufacture IUP devices. No preventative maintenance plan was provided upon request. The Instruction Manual (Exhibit R118.1-118.10, select pages included) states under the Maintenance section that the windows on the mike should be cleaned, ' [illegible] ' The extruder system, including laser mike were observed in operation on 3/4/03.

16.B. The [illegible] packaging machine is used to package IUP catheters into [illegible] lids. IUP catheters are sterile devices.

The preventative maintenance (PM) procedure for this piece of equipment was requested. The last [illegible] PMs were provided (Exhibit R119.1-119.2). Mr. Smith explained that the procedure is outlined on the PM sheet. The PM states to clean suction cups, check vacuum pump oil, grease all lube points, and do an over all inspection for any problems. The PM procedure does not make any reference to the equipment Operations/Parts Manual.

Select pages of the Operations/Parts Manual were collected (Exhibit R120.1-120.3). The manual directs maintenance on specific parts of the equipment, including the [illegible] (Exhibit R120.2-120.3). UTMD's PM procedure for the [illegible] machine is not specific as to all areas that should be inspected and potentially maintained. Further, the PM report (Exhibit R119.1-119.2) does not indicate what work was actually performed (i.e. what was oiled, inspected, repaired or replaced).

16.C. PM records for the Static Control Mats were requested. The last [illegible] PMs were reviewed (Exhibits R106.1-106.3). The PM indicates that static control mats are located in the [illegible] and [illegible] areas. The PM does not state that all [illegible] areas are maintained on each PM work order.

PM work order [illegible] dated [illegible] does not indicate how much of the work order was completed under the ' [illegible] section of the PM (Exhibit R106.1); although, the work order was signed by [illegible]

The PM directs the Craftsman to the instructions in the, (Exhibits R121.1-121.17), pages . These pages include instructions for Periodic Performance Testing, Qualification, and Evaluation of Static Control Materials. However, the Evaluation of Static Control Materials does not end on page , it ends on page It is unknown if the operator is conducting this test as the PM does not specifically identify each test the Craftsman is to perform.

The PM does not make reference to the unidentified document (Exhibit R122) provided by Mr. Shirley during the inspection and identified as the firm's calibration procedure for ESD equipment. (See Observation 18).

The PM does not indicate what locations on each mat are calibrated or even if each mat in each work area is calibrated (Exhibit R106.1-106.3).

Finally, the PM does not indicate that a surface inspection of the mat is conducted. Mats in the room were observed to have holes, burns, nicks and cuts in the surface. The PM does not contain enough information to determine if the mats were functioning or capable of being calibrated.

16.D. Procedure , Housekeeping, Section (Exhibit R117.5-117.6) requires tacky mats at various locations. Tacky mats were observed to be located outside of and the room. Mats are to be changed

Cleaning activities listed in the chart in Section are to be performed by housekeeping personnel.

Section under Documentation of Cleaning Activities states that Form shall be filled out by Housekeeping , Form shall be filled out by Housekeeping each and Form shall be filled out by Housekeeping each (Exhibit R117.4).

Dirty tacky mats were observed on 2/24/03 outside of clean rooms and on 3/6/03 a dirty tacky mat was observed inside the door to the EA room.

I requested documentation that the tacky mats are being changed at least as required by the procedure. No documentation was provided.

16.E. During a tour of the EA room on 2/24/03, it was noted that the cleaning log had not been completed for the (Exhibit R123). The log is to be complete by production personnel according to SOPs Housekeeping (Exhibit R117.4) and SOP FORM , Cleaning Log Manufacturing Areas (Exhibit R124.1-124.3).

UTMD's general SOP for Preventative and Unscheduled Maintenance, [redacted] Rev. [redacted] is included (Exhibit R125.1-125.3). Additional examples of PMs are also included (Exhibits R126; R127.1-127.4; R128.1-128.2; R129.1-129.4; R130.1-130.2; R131).

Related Exhibits:

16.A. R118.1-118.10

16.B. R119.1-119.2; R120.1-120.3

16.C. R36.1-36.23; R101.1-101.12; R102.3; R103.2; R106.1-106.3; R117.5-117.6; 117.4; R121.1-121.17; R122

16.D. R117.5-117.6

16.E. R117.4; R123; R124.1-124.3; R125.1-125.3; R126; R127.1-127.4; R128.1-128.2; R129.1-129.4; R130.1-130.2; R131

OBSERVATION 17

There is incomplete documentation of the equipment identification for measurement equipment .

Specifically,

The [redacted] Certificate of Calibration, test No. [redacted] for calibration of the [redacted] Laser Mike in use on the extruder, contained the incorrect equipment ID No. [redacted] and the incorrect model number [redacted]

Annotation:
17. Corrected but not verified
Reference: 21 CFR 820.72(b)(2)

Observation 17 was made by Investigator Chase-Off.

Relevance:
This Observation relates to equipment used as part of the extrusion molding system used to extrude [redacted] tubing for manufacture of IUP devices. The firm operates [redacted] laser mikes.

Discussion with management:

I requested the equipment calibration during the inspection. When I explained to Mr. Shirley that the numbers on the certificate did not match the numbers on the equipment he stated that he realized that and that he had already taken measures to correct the problem.

During the close-out, Mr. Shirley again stated that he had taken corrective action. I told all present that the correction would be verified at a later date.

Additional details of the observation:

The [redacted] laser micrometer (mike) is used as part of the extrusion molding system to measure the diameter of tubing as it exits the printer from the extruder. The calibration certificate (Exhibit R132.1-132.2) does not match the identification number or model number of the equipment.

The firm's general SOP for Calibration of Measuring Equipment, [redacted] Rev [redacted] is included (Exhibit R133.1-133.5).

Related Exhibits:

17. R132.1-132.2; R133.1-133.5

OBSERVATION 18

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.

Annotation:

18. Promised to correct within [redacted]

Observation 18 was made by Investigator Chase-Off.

Reference: 21 CFR 820.40(a)

Relevance:

This Observation pertains to document control, a system that affects all devices manufactured by UTMD. More specifically, the document referenced in the Observation applies to calibration of the

electrostatic discharge system (ESD) that is used in the [redacted] room where Finesse and Liberty devices are manufactured.

Discussion with management:

During the inspection, Mr. Shirley provided an untitled document (Exhibit R122) stating that it was used to calibrate the ESD system. I told Mr. Smith and Mr. Shirley, during the inspection, that the document needed to be part of the document control system.

At the close-out, Mr. Smith acknowledged our previous conversations and agreed that the document would be made a controlled document as part of the document control system. Mr. Cornwell concurred.

Additional details of the observation:

The document does not have a title and does not state what the procedure is used for (i.e. calibration of the ESD system or functionality testing of the ESD system) (Exhibit R122). However, the document was provided by Mr. Shirley when I requested documentation of preventative maintenance, and calibration performed on the ESD system.

Related Exhibits:

18. R122

OBSERVATION 19

Quality audits did not verify that the quality system is effective in fulfilling your quality system objectives.

Specifically,

Procedure [redacted] Rev [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 [redacted] CAR, number [redacted] nd a product recall [redacted] only. 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.

Annotation:

19. Corrected but not verified

Observation 19 was made by Investigator Chase-Off.

Reference: 21 CFR 820.22

Relevance:
This Observation relates to the effectiveness of the firm's internal quality audits, specifically the Corrective and Preventive Action system (CAPA). CAPA is a system that monitors the quality of all products that UTMD manufactures. Observation 12 of the 4/15/02, FDA-483 addressed the inadequacies of the firm's Internal Audit procedure (Attachment R12.6).

Discussion with management:
Mr. Smith provided the firm's current Internal Audit Procedure, [redacted], Rev. [redacted] dated [redacted] (Exhibit R134.1-134.5), which will be used for audits conducted in [redacted] During the close-out meeting, Mr. Smith indicated that he feels the current audit procedure addresses the need for more detail in the audit procedure and process.

I told all present that the SOP has not been verified as effective because no audits had been conducted under the procedure and that audits would be evaluated at a future inspection to determine if the change in procedure was truly effective in correcting the Observation.

Additional details of the observation:
Mr. Smith provided a schedule for the firm's [redacted] internal quality audits (Exhibit R135). Audits are were not scheduled to begin until [redacted] therefore, I reviewed quality audit plans for [redacted]

According to the firm's procedure [redacted], Rev. [redacted] effective [redacted] (Exhibit R136.1-136.4), each auditor is to create an audit plan outlining what specific items will be audited. Further, the SOP states that Form [redacted] is to be used to, [redacted] " and any other items that may be investigated during the audit (Section 4.5, Exhibit R136.3).

Audit plans were reviewed for Process Controls – Deltran, Process Controls – Molding, Customer Complaints, and Corrective and Preventive Action (Exhibits R137; R138; R139.1-139.2; R140).
Note that the Process Controls audit plans (Exhibits R137 and R138) clearly state which sections of 21 CFR 820 apply to the system being audited. The Customer Complaints and Corrective and Preventive Action plans (Exhibits R139.1-139.2 and R140) do not state what sections of 21 CFR 820 apply, as required by procedure.

The Corrective and Preventive Action internal audit plan states that [redacted] and recall [redacted] were reviewed. The audit plan does not indicate that the items reviewed were adequate to ensure

that the Corrective and Preventive Action system is functioning to the extent required by the firm's SOP for Corrective/Preventive Action (Exhibit R33.1-33.5) or 21 CFR 820.

UTMD's 2002 audit schedule is included (Exhibit R141).

Related Exhibits:

19. R33.1-33.5; R134.1-134.5; R136.1-136.4; R137; R138; R139.1-139.2; R140

REFUSALS

See Additional Information, Production and Process Controls, Item 1.

GENERAL DISCUSSION WITH MANAGEMENT

Written by CSO Chase-Off

On 2/24/03, Mr. Cornwell asked many questions regarding the reason for our presence in the firm. I explained to Mr. Cornwell that we were conducting a follow-up to the previous FDA-483, we were trying to answer some specific questions that CDRH personnel had, and we were going to review and evaluate current operations.

Mr. Cornwell asked that we hold daily close-out meetings to keep him apprised of how the inspection was progressing, if there were any issues and if we were getting the documentation that we needed.

I told Mr. Cornwell that we would have the daily meetings but that I was not going to go over an entire day's conversations and events. Further, I told Mr. Cornwell that I would rely on Mr. Smith, as the Quality Manager, to keep Mr. Cornwell fully informed of the day's happenings.

Daily close-out meetings were held with Mr. Cornwell, Mr. Shirley and Mr. Smith on all days except 2/24/03. On that day, we did not have tape recording equipment available. The close-out discussion for 2/24/03 was held on 2/25/03.

On 3/5/03, the tapes were not recording during the daily close-out meeting; although, discussions were held. On 3/6/03, we briefly discussed the items of 3/5/03 for the taped record.

Daily close-out tapes are included with the **Original EIR** only. (Exhibits R179.1-179.6)

On 3/12/03, I asked to review the original documents supporting collected for DOC 199272. I initialed and dated the back side of each original collected for the documentary sample. I informed Mr. Cornwell that I had done this, as he was not present at the time of my initialing.

Prior to beginning the close-out meeting on 3/12/03, Mr. Cornwell reviewed but would not sign the Affidavit accompanying Documentary sample DOC 199272. Mr. Cornwell stated that he did not understand the legal language at the top of the Affidavit form and therefore, preferred not to sign the document. He did acknowledge that the documents referenced in the Affidavit were those reviewed and collected during the inspection.

At Mr. Cornwell's request and in agreement with the DEN-DO District Director, Director of Investigations and the Director of Compliance, Mr. Cornwell was allowed twenty minutes in private to review the FDA-483 prior to discussing it with myself and Investigator Coleman.

Before beginning the presentation of the FDA-483, Mr. Cornwell posed questions and made opening remarks. Mr. Cornwell asked if we could agree the Observations were not violations of the FD&C Act. I told Mr. Cornwell the Observations were just that, Observations made by the Investigators during the inspection.

Mr. Cornwell asked to have a Compliance Officer available by telephone to provide direct reference to 21 CFR 820 for each Observation on the FDA-483. Mr. Cornwell stated that he had not had the benefit of having citation information provided to him in the past for Observations and was seeking that benefit during this inspection. I told Mr. Cornwell a Compliance Officer would not be made available.

Mr. Cornwell wanted to know if 21 CFR Part 820 requires the company to identify violations. Investigator Coleman and I chose not to comment on Mr. Cornwell's question.

On 3/6/03, at the daily close-out meeting, Mr. Cornwell had asked me to go back over the list of discussion items from 3/5/03, a day when our tape recorders were not running. At the FDA-483 close-out meeting, Mr. Cornwell informed me that my review on 3/6/03 was vague, overly general, inaccurate, misleading and in some cases false.

Mr. Cornwell stated that he has reviewed the Kim Trautman book I referred him to during the previous inspection (The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices). Mr. Cornwell stated that he reread the preamble to the QSR.

Mr. Cornwell referred to the 1997 Guide to Inspections and particularly read from sections referencing small firms and businesses. Mr. Cornwell inferred that UTMD is a small business and is not to be held to the same level of documentation as a large company would be. Further, Mr. Cornwell referred to sections stating that detailed written procedures may not be necessary.

Mr. Cornwell then referred to 519(a)(4) of the FD&C Act stating that the Act prohibits record keeping requirements that are unduly burdensome to a device manufacturer.

After the presentation of the FDA-483 items, Mr. Cornwell requested a copy of the "assignment" from CDRH. I told Mr. Cornwell that I would not provide a copy of that document. Mr. Cornwell wanted to know if he had provided all the documentation necessary to answer the questions posed by CDRH. We told him that we had no comment.

Mr. Cornwell stated that he wished he would have had the previous EIRs sooner so that he could have offered comments.

Mr. Cornwell stated that it was unfortunate that the District Supervisors did not give him the benefit of an open dialogue. Mr. Cornwell expressed his hope that this inspection was useful to clarify the prior EIRs.

Mr. Cornwell stated that he trusted that we would be fair and objective in our EIR, and asked if we believed UTMD was in an overall state of control. Investigator Coleman stated that we should not comment on Mr. Cornwell's question. He asked if that meant that Investigator Coleman felt UTMD was not in a state of control.

Ms. Coleman told Mr. Cornwell that the report would be reviewed by Supervisors and Compliance. Mr. Cornwell pressed for an opinion from Investigator Coleman. I told Mr. Cornwell that we are not allowed to comment one way or another regarding the firm's state of compliance.

I informed all present that FDA has certain remedies available to it to ensure compliance with the Quality System Regulation and the Food, Drug and Cosmetic Act, including no action, Warning Letter, seizure of product, injunction, civil money penalties and criminal prosecution. Further, that the Agency may take action at anytime without any previous notice being given, and that, the Agency may take action in at any level.

Mr. Cornwell's response was, "so noted".

INSPECTIONAL GUIDANCE

Inspectional Guidance was provided from CDRH (Attachment 15.1-15.4). Discussion of each Inspectional Guidance item is noted below. (KAC- Written by Investigator Coleman; RACO-Written by Investigator Chase-Off)

1-2. KAC

See discussion on FDA-483 items: 1 A 1, 1 A 2, and 1 AB for sterilization validation.. See discussion on FDA-483 items 7. A,B, C. D for environmental conditions that may impact sterilization.

The firm's procedures require a revalidation or reassessment as per ***Exhibit K 20.1- K 20.4,*** ***Rev*** ***STERILIZATION, dated*** see section 5]. The last reassessments were done

The last physical validation work was a performed because of the chamber data printout change See the table in the EIR under FDA 483 item 1. A. 1 "Summary of Validation/Revalidation Assessments for additional information.

The overall validity of the firm sterilization validation is questionable because of the problems noted with the firm's comparative resistance studies [CRS] see discussion on FDA 483 item 1 A 1, FDA 483 1A 2, and supporting evidence.

The following Exhibits are attached to the EIR as supporting evidence:

K 1.1	IUP Plus, Dual Lumen Tubing, 30.5 IN
K 2.1-K 2.4	IUP Brochure (4 pp)
K 3.1	LAB FILE dated List of Comparative Resistance Studies
K 4.1- K 4.7	Comparative Resistance Study Laboratory No.
K 5.1-K 5.8	Comparative Resistance Study Laboratory No.
K 6.1	
K 7.1-K 7.7	Comparative Resistance Study Laboratory
K 8.1-K 8.7	Comparative Resistance Study Laboratory
K 9.1-K 9.7	Comparative Resistance Study Laboratory
K 10.1-K 10.18	Comparative Resistance Study Laboratory
K 11.1-K 11.2	
K 12.1-K 12.3	
K 13.1-K 13.6	
K 14.1-K 14.6	
K 15.1-K 15.9	
K 16.1-K 16.4	
K 17.1-K 17.2	
K 18.1-K 18.3	
K 19.1-K 19.3	

K 20.1-K 20.4 STERILIZATION, Date
K 21.1-K 21.32 Revalidation Assessments [selected pages] for
K 22.1-K 22.30 ; Bioburden Lab Report No. and other selected pages
K 23.1-K 23.21 Validation [selected pages] includes Master Product
K 24.1-K 24.32 Validation [selected pages] includes Master Product
K 25.1-K 25.4 INTRAN 500 Final Design Review, dated
K 26.1-K 26.3 INTRAN 500 Final Design Review Summary, dated
K 27.1-K 27.9 Project File Memo for FMECA dated
K 28.1-K28.15 AAMI METHOD 1 DOSE AUDIT LAB REPORT NO.
K 29.1-K 29.13 CHANGE PROPOSAL NUMBER 0
K 30.1-K 30.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 31.1- K 31.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 32.1-K 32.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 33.1-K 33.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 34.1-K3 4.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 35.1-K 35.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.
K 36.1-K 36.7
K 37.1-K 37.5
K 62.1- K 62.11 FINAL PRODUCT AND SUBASSEMBLY RELEASE, Dated

3. RACO

UTMD has not done real time shelf life studies to support the five year expiration date on IUP devices. Accelerated aging has been done; however, there are no test protocols for real time shelf life studies and no devices have been put on real time studies. (See FDA-483, Observation 12) UTMD has attempted a real time shelf life study to evaluate device packaging however, that study and test protocol are inadequate. (See FDA-483, Observation 1.C.1. and 1.C.2.)

4. RACO

DHRs were reviewed dating from All DHRs reflected the appropriate expiration date that was in effect, according to UTMD's procedures and test data, at the time of manufacture.

5. KAC

Molding Operations: The firm could not provide any evidence they had ever validated their extrusion or injection molding operations. They claimed it was done and they were given several days to look through archive files. They never submitted anything for review by the closeout and confirmed they could not find anything. See FDA 483 items 1 D 1 & 2 with the Exhibits referenced below:

K 38.1 Molding room equipment layout diagram

K 39.1-K 39.3 WORK ORDER TRAVELER ASSEM

K 40.1-K 40.7 , EXTRUSION SET-UP, Dated

K 41.1-K 41.12 , EXTRUSION RUNNING PROCEDURE, Dated

K 42.1- K 42.6 EXTRUSION CLEANING PROCEDURE, Dated

K 43.1- K 43.4

K 44.1- K 44.2 MOLDING SET-UP SHEET for machine number (2 pp)

K 45.1

K 46.1 , IN-PROCESS MOLD MAINTENANCE sheet dated

K 47.1- K 47.3

K 48.1-K 48.3 MANUFACTURING LINE CLEARANCE, Dated

K 49.1-K 49.5 MOLDING MATERIAL HANDLING, Dated

K 50.1- K 50.8 WORK-ORDER BUILD, Dated

K 51.1- K 51.4

K 52.1-K 52.3

K 53.1-K 53.14

K 54.1- K 54.5 , INJECTION MOLD INSTALLATION AND REMOVAL, Dated
page was not provided to FDA with the copy of this document]

K 55.1- K 55.3 RUN SHEET-MOLDING, Dated

K 56.1- K 56.4 INJECTION MOLDING PROCESS SET-UP AND PRODUCING PARTS, Dated

K 57.1 SETUP SHEET MOLDING SET-UP SHEET

K 58.1- K 58.3

K 59.1- K 59. , MOLDING AND EXTRUSION INSPECTION PROCEDURE, Dated

K 60.1-K 60 MOLDING DEPARTMENT MOLDED PART HANDLING, Dated

K 61.1- K 61.5Q LABEL RECONCILIATION AND VERIFICATION, Dated

K 62.1- K 62.11 , FINAL PRODUCT AND SUBASSEMBLY RELEASE, Dated

6. RACO

At the time of the last inspection (3/25-4/15/02), SOP Corrective/Preventive Action was in force (Exhibit R142.1-142.3). However, documents collected during the previous inspection, specifically Corrective and Preventive Action Request form , were of SOP . SOP was collected to demonstrate the complete procedure for creating a corrective and preventive action request (Exhibit R143.1-143.5). The SOP only describes how to complete the form, it does not describe the entire Corrective and Preventive Action system.

The current procedures for creating form[illegible] (Exhibit R142.1-142.3) and for the Corrective and Preventive Action [illegible]stem (Exhibit R33.1-33.5) are included.

Observations 2-5 on the current FDA-483 reflect insufficiencies with the Corrective and Preventive Action system and procedures.

7. RACO

Mr. Smith and Mr. Cornwell stated that all documentation relating to the evaluation of patient risk and product evaluation, in response to cracking/brittle IUP catheter investigations, has been submitted in UTMD's response to the previous FDA-483, dated 4/15/02.

No further documentation was provided by Mr. Cornwell or Mr. Smith during the current inspection. As directed this Observation was included as FDA-483 item 4.

8. RACO

The reference to "[illegible] is not a document reference. [illegible] is a data screen in the [illegible] software system that controls [illegible]t. For example, [illegible] MWO-04, in Dataworks.

After the previous inspection, UTMD personnel completely revised the [illegible]

A review of current DHRs for IUP manufacturing indicated that all devices are now accounted for in the DHR on the BOO.

[illegible] entry may be referenced in the current production procedures; [illegible] Each step of the production process is controlled by a procedure that is referenced on the [illegible] A[illegible] for IUP-400 manufacturing is included as an example (Exhibit R148.1-R148.4).

Any procedures not already referenced in this EIR are included here to provide a complete review of the current IUP manufacturing process (Exhibits R145-R159).

It should be noted that the [illegible]software system has not been validated. (See FDA-483 Observation 2)

9. RACO

The current DMR (Exhibit R14.1-14.8) has been corrected to reflect

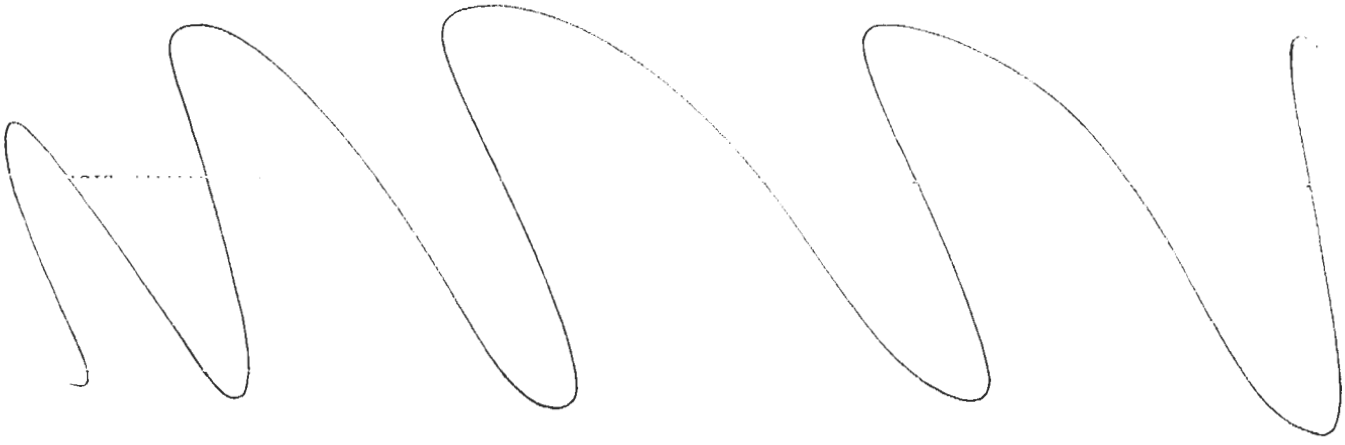
10. RACO

Deltran and ABC kit cracking complaints were reviewed. The complaints of cracking dealt with injection molded parts These complaints of cracking were not related to or caused by gamma irradiation or materials. Most of the cracking complaints dealt with molding issues.

11. RACO

The complaints reviewed during the previous inspection were reviewed again. Complaints (Exhibit R75.1-75.7), (Exhibit R68.1-68.5), (Exhibit R65.1-65.8) and (Exhibit R80.1-80.11) referenced cracked/brittle catheters

Recent complaints) were also reviewed.



Mr. Cornwell, Mr. Smith and Mr. Shirley all contend that any [redacted] catheters that are brittle or cracking were [redacted]; and that there have been no confirmed complaints of cracking catheters [redacted].

Mr. Cornwell and Mr. Smith believe that the firm's corrective action has been effective and no further action is necessary. [redacted]

12. RACO

Complaints for [redacted] were reviewed. [redacted] complaints did not relate to cracking complaints. Most of the [redacted] complaints dealt with [redacted] that where the [redacted] was cracking and coming off the device. [redacted] Some cracking complaints on Deltran and ABC, for example, dealt with cracking of injection molded parts such as luers.

UTMD does not maintain definitions for the failure codes used to track complaints and the Complaint procedures (Exhibits R31.1-31.9; R32.1-32.6) do not describe how to use the failure codes to ensure consistency.

Duplicate or undefined use of failure codes is documented for Finesse in FDA-483 Observation 3.A.1.

Regarding cracking/brittle catheters, Mr. Smith stated that the firm switched from "cracking" to "brittle", exclusively after the last establishment inspection. Mr. Smith stated that he terms are not defined but that he and the engineers had discussed the terms and decided that brittle is a more accurate term for the failure.

KAC

Review of [redacted] [Finesse] complaints revealed problems. See discussion on FDA 483 item 3 A, B, and C including but not limited to CAPA problems with the procedures, failure coding, problems that might prevent the firm from identifying existing problems and detecting recurring problems.

See the following Exhibits:

K 63.1- K 63.5 [redacted] CORRECTIVE/PREVENTIVE ACTION, Dated [redacted]
K 64.1- K 64.3 [redacted] CORRECTIVE/PREVENTIVE ACTION REQUEST, Dated
K 65.1- K 65.9 [redacted] CUSTOMER COMPLAINT SYSTEM, Dated [redacted]
K 66.1- K 66.6 [redacted], CUSTOMER COMPLAINT INVESTIGATION, Dated
K 67.1- K 67.12 COMPLAINT #
K 68.1- K 68.8 COMPLAINT #
K 69.1- K 69.9 COMPLAINT #
K 70.1- K 70.9 COMPLAINT #
K 71.1- K 71.13 COMPLAINT #
K 72.1 - K 72.15 COMPLAINT #
K 73.1- K 73.22 COMPLAINT #
K 74.1 - K 74.4 COMPLAINT #
K 75.1 - K 75.9 COMPLAINT #
K 76.1- K 76.17 COMPLAINT #
K 77.1- K 77.15 COMPLAINT #

13. RACO

This item is related to Inspectional Guidance item 7. Mr. Smith and Mr. Cornwell believe that the complaint investigations and UTMD's response to the previous FDA-483 address this question. Mr. Cornwell does not believe that any further documentation is necessary to explain the rationale behind the firm's decision that the device failure would not cause serious patient injury.

14. RACO

All procedures for IUP manufacturing have been revised since the previous inspection. [redacted] However, some UTMD procedures for IUP manufacturing call for engineering review, while most do not. This item is discussed as FDA-483, Observation 3.B.

Further, during the inspection, Mr. Cornwell presented data on scrap rates and cost analysis. Mr. Cornwell demonstrated that [redacted] for IUP manufacturing. However, we had some discussion on what was expected for failure analysis.

PURGED

I explained, as an example, that there was a difference between product that fell on the floor and could not be used and product that failed an in-process test or specification. I went on to explain that devices that fail in-process tests should be evaluated to determine why the devices failed.

Procedures that call for an engineering review, should result in that review being documented and data from that review evaluated to determine if they relate to product quality or if those data need to be tracked. I told Mr. Cornwell that one way data from engineering evaluation could be tracked would be using an engineering notebook.

Mr. Cornwell stated that not all failures of in-process tests are failures and not all in-process tests are acceptance activities. Mr. Cornwell stated that devices that are rejected account for so few that they don't hit the "significance radar". If they are insignificant in terms of cost then Mr. Cornwell inferred that he does not believe those rejects/scraps need to be evaluated.

15 RACO

I asked for the design control documentation evaluating the problem with th Mr. Shirley provided notebooks. (Exhibits R160.1-160.16). This documentation goes back to It should be noted that none of the design control documents state why a

The problem with the dates back to , as documented (Exhibit R46.3-46.4). The design projects were last documented in Exhibit R160.16).

Mr. Shirley stated that

Mr. Smith stated that the User Guidelines manual is not distributed with each device, usually one manual is provided to each customer.

I asked Mr. Cornwell if there was a user notice sent regarding the change in the User Guidelines for this problem (Attachment 11.1). Mr. Cornwell replied that UTMD did not notify users of the change in the User Guidelines manual (Exhibit R2.1-2.24).

16. RACO

17. RACO

UTMD's quality audit procedures now refer to the QSR as well as ISO as the standards for compliance.

18. RACO

Interstate documentation, including incoming raw materials received on a Bill of Lading, was collected and is provided in DOC 199272.

ADDITIONAL INFORMATION

Written by CSO Chase-Off

Management Review

Management review is performed per SOP, [redacted] Management Review of Quality System (Exhibit R162.1-162.3)

UTMD held its [redacted] Management Review for the year [redacted]. The agenda for this meeting is provided (Exhibit R163.1-163.14). Note that Exhibit R163 does not represent the meeting minutes only the agenda items. Areas that are blacked out contained internal audit findings.

The agenda states that UTMD was audited by [redacted] and observations discussed included [redacted] and our [redacted] (Exhibit R163.2) [redacted] Exhibit R163.6).

Exhibits R163.9-R163.14 demonstrate data analyzed and presented for management review.

Corrective and Preventive Action (CAPA)

UTMD holds meetings of the Materials Review Board (MRB) to decide what actions will rise to the necessity of having a Corrective/Preventive Action initiated. Exhibit R164.1-164.21 is included to provide additional information not already provided elsewhere on what types of data are collected and reviewed by Quality personnel.

Production and Process Controls

1. During tours of the room on 2/24/03, 2/27/03 and 3/6/03, handwritten notes were observed on tablets and post-its. These notes included information on Finesse serial numbers, model numbers and test results.

On 2/27/03, we requested a copy of notes observed in the room. The notes were written by the Engineer, Mr. Cornwell refused to provide a copy of the notes stating that they were "personal" notes and not quality data.

On 2/28/03, after being told that we considered the failure to provide the notes a "refusal", Mr. Cornwell agreed to let us review the notes. However, Mr. Cornwell stated that the notes were personal and would normally have been discarded.

The note contained the following information:

The was collected that documents the notes above (Exhibit R168.1-168.2). The form has not been signed as complete, but it should be noted that the serial numbers of the components were not contained in the Report.

Investigator Coleman explained that the "personal" notes contained original data of and that those data should be retained as part of the original documentation. Mr. Cornwell continued to disagree, stating that the notes were personal.

On 2/24/03, when I first observed the notes in use on the lab bench in the room, the Engineer, was present. I asked him what he does with the notes and he replied that the notes are discarded when he is done with them.

Investigator Coleman asked about the information on a handwritten note Investigator Coleman was told it was information for he made on a unit to make a

2. Post-inspectional review revealed that SOP, states to use templates (Exhibit R19.2/19.4). is provided (Exhibit R169). According to . UTMD no longer uses the being used , is a with no necessary. and SOP, do not represent the current procedures being used in production.

VOLUNTARY CORRECTIONS

Written by CSO Chase-Off

On 3/26/03, Mr. Shirley arrived at the Residence Post unannounced and provided two documents.

The first document is a Preventative Maintenance plan for This document was provided in response to FDA-483 Item 18. Mr. Shirley stated that the "untitled" document has been replaced with this PM document (Exhibit R177).

The second document provided is SOP, (Exhibit R178). Mr. Shirley stated that this document was provided in response to FDA-483 Item 7.F. The SOP has been changed such that documentation

FDA-483 Item 16.E. was noted as Corrected but not verified at the close-out of the inspection. The daily cleaning log was observed to have been completed once the deficiency was brought to the attention of Mr. Smith and Mr. Shirley. I explained that the Observation would be verified corrected if the same or similar observations are not made during the next establishment inspection.

FDA-483 Item 17 was noted as Corrected but not verified at the close-out of the inspection. Mr. Shirley acknowledged during the inspection that the calibration records for the contained wrong information for identifying the equipment and stated that the information would be corrected. At the close-out meeting Mr. Shirley stated that the record had been corrected but the record was not verified by myself.

FDA-483 Item 19 was noted as Corrected but not verified at the close-out of the inspection. Mr. Smith stated that he believes the firm's

remedy the Observation. I told Mr. Smith that the correction would be confirmed on subsequent inspection if no similar observations are made regarding the adequacy of UTMD's Internal Audit policy or performance.

Corrections made to FDA-483 items from 4/15/02 are noted under Inspectional Guidance items, 4, 8, 9, 16 and 17.

EXHIBITS AND SAMPLES COLLECTED

There are two sets of Exhibits included with this EIR; those submitted by Investigator Coleman and those submitted by myself, Investigator Chase-Off. Investigator Coleman's exhibits are numbered beginning with a "K". Investigator Chase-Off's exhibits are numbered beginning with the letter "R".

Exhibits Submitted by Investigator Coleman "K"

K 1.1 IUP Plus, Dual Lumen Tubing, 30.5 IN
K 2.1-K 2.4 IUP Brochure (4 pp)
K 3.1 LAB FILE dated , List of Comparative Resistance Studies
K 4.1- K 4.7 Comparative Resistance Study Laboratory No.
K 5.1-K 5.8 Comparative Resistance Study Laboratory No.
K 6.1 ; Kit dated
K 7.1-K 7.7 Comparative Resistance Study Laboratory No.
K 8.1-K 8.7 Comparative Resistance Study Laboratory No
K 9.1-K 9.7 Comparative Resistance Study Laboratory No.
K 10.1-K 10.18 Comparative Resistance Study Laboratory No.
K 11.1-K 11.2
K 12.1-K 12.3
K 13.1-K 13.6
K 14.1-K 14.
K 15.1-K 15.9 Forms: [Lab Submission Form] [BI Location Maps for
K 16.1-K 16.4 MASTER PRODUCT BIOLOGICAL INDICATOR SAMPLES, dated
K 17.1-K 17.2 for BI-STERILITY TEST KIT
K 18.1-K 18.3 BACTERIAL TEST STRIP,
K 19.1-K 19.3
K 20.1-K 20.4 STERILIZATION,
K 21.1-K 21.32 Revalidation Assessments [selected pages] for
K 22.1-K 22.30 Revalidation for change in data printout; Bioburden Lab Report No. and other selected pages
K 23.1-K 23.21 Validation [selected pages] includes Master Product BI diagram)
K 24.1-K 24.32 Validation [selected pages] includes Master Product BI diagram
K 25.1-K 25.4 INTRAN 500 Final Design Review,
K 26.1-K 26.3 INTRAN 500 Final Design Review Summary,

K 27.1-K 27.9 Intran 500 Project File

K 28.1-K 28.15 AAMI METHOD AUDIT LAB REPORT

K 29.1-K 29-13 CHANGE PROPOSAL NUMBER

K 30.1-K 30.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.

K 31.1- K 31.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No

K 32.1-K 32.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.

K 33.1-K 33.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.

K 34.1-K 34.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.

K 35.1-K 35.6 LIMULUS AMEBOCYTE LYSATE (LAL) TEST Laboratory No.

K 36.1-K 36.7 WO

K 37.1-K 37.5

K 38.1 Molding room equipment layout diagram

K 39.1-K 39.3 WORK ORDER TRAVELER ASSEM

K 40.1-K 40.7 EXTRUSION SET-UP,

K 41.1-K 41.12 EXTRUSION RUNNING PROCEDURE

K 42.1- K 42.6 EXTRUSION CLEANING PROCEDURE.

K 43.1- K 43.4 Work Order Traveler [WO] and picklist for WO

K 44.1- K 44.2 MOLDING SET-UP SHEET for machine number

K 45.1 Form RUN SHEET in use on for part numbe on machine number with mold numbe

K 46.1 Form IN-PROCESS MOLD MAINTENANCE sheet dated for Work Order #

K 47.1- K 47.3

K 48.1-K 48.3 MANUFACTURING LINE CLEARANCE

K 49.1-K 49.5 MOLDING MATERIAL HANDLING

K 50.1- K 50.8 WORK-ORDER BUILD

K 51.1- K 51.4 REGRIND PROCEDURES,

K 52.1-K 52. MATERIAL DRYER CLEANING AND START UP

K 53.1-K 53.14 PROCEDURE FOR PRINTING LABELS ON

K 54.1- K 54.5 INJECTION MOLD INSTALLATION AND REMOVAL,

K 55.1- K 55.3 RUN SHEET-MOLDING

K 56.1- K 56.4 INJECTION MOLDING PROCESS SET-UP AND PRODUCING PARTS, Dated

K 57.1 SETUP SHEET MOLDING SET-UP SHEET

K 58.1- K 58.3

K 59.1- K 59.3 MOLDING AND EXTRUSION INSPECTION PROCEDURE,

K 60.1-K 60.5 MOLDING DEPARTMENT MOLDED PART HANDLING,

K 61.1- K 61.5 LABEL RECONCILIATION AND VERIFICATION,
K 62.1- K 62.11 FINAL PRODUCT AND SUBASSEMBLY RELEASE,
K 63.1- K 63.5 CORRECTIVE/PREVENTIVE ACTION,
K 64.1- K 64.3 CORRECTIVE/PREVENTIVE ACTION REQUEST,
K 65.1- K 65.9 , CUSTOMER COMPLAINT SYSTEM,
K 66.1- K 66.6 CUSTOMER COMPLAINT INVESTIGATION,
K 67.1- K 67.12 COMPLAINT
K 68.1- K 68.8 COMPLAINT
K 69.1- K 69.9 COMPLAINT
K 70.1- K 70.8 COMPLAINT
K 71.1- K 71.13 COMPLAINT
K 72.1 - K 72.15 COMPLAINT
K 73.1- K 73.22 COMPLAINT
K 74.1 - K 74.4 COMPLAINT
K 75.1 - K 75.9 COMPLAINT
K 76.1- K 76.17 COMPLAINT
K 77.1- K 77.15 COMPLAINT
K 78.1 –K 78.4 MICROBIAL BIOBURDEN TESTING OF DEVICES,

K 79.1-K 79.78 Bioburden Report Lab and related DHR's including but not limited to:

K 80.1- K 80.55 Bioburden Lab NO and related DHR's including but not limited to:

K 81.1- K 81.5 Bioburden Lab NO.
K 82.2 - K82.5 Bioburden Lab NO.
K 83.1- K 83.6 Bioburden Lab NO.
K 84.1 MEMORANDUM
K 85.1- K 85.8 MEMORANDUM
K 86.1- K 86.5 Bioburden Lab NO.
K 87.1- K 87.31 SOP
K 88.1- K 88.26 SOP/
K 89.1- K 89.10 ENVIRONMENTAL CONTROL AND MONITORING,
K 90.1-K 90.3 Bioburden Lab
K 91.1-K 91.8 Presterilization Bioburden Counts Lab
K 92.1 PARTS DESCRIPTION FOR LABORATORY NUMBER
K 93.1-K 93.6 Form Specification Rev ENVIRONMENTAL TEST RESULTS, FOR

K 94.1- K 94.2 , ACCEPTABILITY OF HANDWASHING WATER
K 95.1- K 95.2 ACCEPTABILITY OF HANDWASHING WATER,
K 96.1- K 96.5 Presterilization Bioburden Counts
K 97.1 PURCHASE ORDER NO. , ORDER DATE from Utah Medical Products Inc. for

Exhibits submitted by Investigator Chase-Off "R"

R1.1-1.3	Labeling: INTRAN PLUS IUP-500
R2.1-2.24	Intran Plus User Guidelines
R3.1-3.17	Human Resources Administration
R4.1-4.32	Annual Report 2001
R5.1-5.26	Quality Manual
R6.1-6.7	General Operational Procedures
R7.1-7.18	Complaint:
R8.1-8.3	Manufacturing Process Qualification and Validation
R9.1-9.5	Test Protocol: Real Time Packaging Integrity Test
R10.1-10.9	Test Report: Real Time Packaging Integrity Test
R11.1-11.10	Work Order
R12.1-12.10	Work Order
R13.1-13.10	Work Order
R14.1-14.8	Intran Sensor Tipped Catheters
R15.1-15.2	Test Protocol: Qualifying Intran Plus For
R16.1-16.8	Test Report: Qualification of Intran Plus For
R17.1-17.3	Test Protocol: IUP / Test
R18.1-18.11	Test Report: Qualification of the For Intran Plus
R19.1-19.9	Intran Catheter -
R20.1-20.4	Test Report: Functionality Test
R21.1-21.14	Test Protocol: Intran Plus Master Test Plan
R22.1-22.4	Lists of requested items.
R23.1-23.3	Document and Data Approval, Issue, and Control
R24.1-24.7	Test Protocol: Document Distribution Systen
R25.1-25.5	Receiving Inspection
R26.1-26.8	Test Protocol:
R27.1-27.12	Change Proposals
R28.1-28.10	Nonconforming Materials
R29.1-29.4	NCMR Form
R30	Internal Memorandum
R31.1-31.9	Customer Complaint System
R32.1-32.6	Customer Complaint Investigation

R33.1-33.5 Corrective/Preventive Action
R34.1-34.9 Returned Goods Procedure
R35.1-35.8 Intran Catheter
R36.1-36.23
R37.1-37.8 Intran Catheter – Final Test
R38.1-38.2 Test Protocol:
R39.1-39.6 Intran Catheter – Testing Plugged Ends
R40.1-40.13 MRB Review Meeting Minutes w/ tables & charts
R41.1-41.16 Corrective/Preventive Action Meeting Minutes w/ tables & charts
R42.1-42.6 - Clean and Inspect
R43.1-43.6 NCMR's
R44.1-44.3 NCMR's:
R45.1-45.3 Corrective/Preventive Action Request:
R46.1-46.4 Vender Rating and Vender Memo
R47 Complaint History for
R48.1-48.4 Complaint:
R49.1-49.3 Complaint
R50.1-50.8 WO#:
R51.1-51.7 WO#:
R52.1-52.9 WO#:
R53.1-53.8 Complaint:
R54.1-54.8 WO#:
R55.1-55.9 WO#
R56.1-56.8 Complaint
R57.1-57.7 WO#
R58.1-58.8 Complaint:
R59.1-59.7 WO#:
R60.1-60.8 Complaint:
R61.1-61.8 Complaint
R62.1-62.5 WO#:
R63.1-63.7 WO#
R64.1-64.11 WO#:
R65.1-65.8 Complaint:
R66.1-66.7 WO#:
R67.1-67.5 WO#
R68.1-68.15 Complaint:
R69.1-69.7 WO#:
R70.1-70.7 WO#
R71.1-71.10 WO#:
R72.1-72.7 WO#:
R73.1-73.10 WO#:
R74.1-74.7 WO#:

R75.1-75.7 Complaint:
R76.1-76.6 WO#:
R77.1-77.6 WO#:
R78.1-78.5 WO#:
R79.1-79.7 WO#:
R80.1-80.11 Complaint:
R81.1-81.7 WO#:
R82
R83.1-83.10 Complaint:
R84 Tip Schematic
R85.1-85.6 WO#:
R86.1-86.6 WO#
R87.1-87.8 WO#:
R88.1-88.14 Complaint:
R89.1-89.5 WO#:
R90.1-90.24 Complaint:
R91.1-91.11 Complaint
R92.1-92.8 WO#:
R93.1-93.7 WO#:
R94.1-94.6 WO#:
R95.1-95.10 Complaint:
R96.1-96.9 WO#:
R97.1-97.5 Intran Catheter -
R98.1-98.12 Complaint
R99.1-99.21 Complain
R100.1-100.7 Post Distribution Monitorin
R101.1-101.12 Permanent Equipment Assembly and Servicing Guideline
R102.1-102.11 Service Procedure
R103.1-103.11 Final Chassis Assembly
R104.1-104.2
R105.1-105.13
R106.1-106.3
R107.1-107.4 Approved Instrument Calibration Procedure
R108.1-108.9 Complaint:
R109 NCMR:
R110 Request for
R111.1-111.9 Intran Catheter -
R112.1-112.14 WO#:
R113.1-113.13 WO#:
R114.1-114.13 WO#:

R115.1-115.9	Test Protocol:
R116.1-116.14	Test Report:
R117.1-117.11	Housekeeping
R118.1-118.10	
R119.1-119.2	WO#'s:
R120.1-120.3	
R121.1-121.17	
R122	Unidentified Document:
R123	Daily Cleaning Log for Production Areas, Manufacturing Midvale:
R124.1-124.3	Cleaning Log Manufacturing Areas
R125.1-125.3	Preventative and Unscheduled Maintenance Procedure
R126	PM WO#:
R127.1-127.4	PM WO#'s:
R128.1-128.2	PM WO#'s
R129.1-129.4	PM WO#'s:
R130.1-130.2	PM WO#'s
R131	PM WO#:
R132.1-132.2	
R133.1-133.5	Calibration of Measuring Equipment
R134.1-134.5	Internal Audit Procedure
R135	Internal Quality Audit Matrix Form
R136.1-136.4	Internal Audit Procedure
R137	Internal Audit Plan: Area of Audit:
R138	Internal Audit Plan: Area of Audit
R139.1-139.2	Memo and Internal Audit Plan: Area of Audit:
R140	Internal Audit Plan: Area of Audit:
R141	Audit Table
R142.1-142.3	Corrective/Preventive Action Request
R143.1-143.5	Corrective/Preventive Action Request
R144.1-144.4	Generic Bill of Operations
R145.1-145.3	Manufacturing Line Clearance
R146.1-146.8	Work-Order Build
R147.1-147.3	
R148.1-148.3	
R149.1-149.4	Intran Catheter –
R150.1-150.4	Intran Catheter –
R151.1-151.6	Intran Catheter –
R152.1-152.7	Intran Catheter –

R153.1-153.7	Intran Catheter -
R154.1-154.6	Intran Catheter -
R155.1-155.5	Intran Catheter -
R156.1-156.3	Intran Catheter -
R157.1-157.5	Intran Catheter -
R158.1-158.3	Intran Catheter -
R159.1-159.6	Intran Catheter -
R160.1-160.16	
R161	Extra Process Work Order:
R162.1-162.3	Management Review of Quality System,
R163.1-163.14	Management Review of Utah Medical Quality System
R164.1-164.21	MRB
R165.1-165.12	Complaint
R166.1-166.6	Complaint
R167.1-167.9	Complaint
R168.1-168.2	Failure Analysis and Repair Report
R169	
R170.1-170.6	W.O.
R171.1-171.5	W.O.
R172.1-172.91	
R173.1-173.11	
R174.1-174.5	Sterility lab report
R175.1-175.4	Sterility lab report
R176.1-176.11	Sterility lab repor
R177	Static Mats (corrective action provided
R178.1-178.12	Permanent Equipment Assembly and Servicing Guidelines,
R179.1-179.6	3 audio cassette recordings of daily close-out meetings (**Original EIR only**)
R180.1-180.6	3 audio cassette recordings of FDA-483 close-out meeting (**Original, CDRH and SLC-RP copies only**)

One sample was collected, DOC 199272, to document interstate commerce and deviations from the QSR. A Memo to supplement DOC 199272 was prepared by CSO Larry Gehring to further document interstate commerce.

ATTACHMENTS

Written by CSO Chase-Off

FDA-482 issued 2/24/03 (1 p.)
FDA-483 reviewed during close-out meeting (13 pp.)
FDA-483 with annotations and corrections, issued 3/12/02 (14 pp.)

FACTS Assignment 385085

R1.1-1.4 UTMD listed products (4 pp.)
R2.1-2.4 UTMD 510(k) list
R3.1-3.3 MDR 415545 (3 pp.)
R4.1-4.3 MDR 395123 (3 pp.)
R5.1-5.3 MDR 394338 (3 pp.)
R6.1-6.2 MedWatch 403866 (2 pp.)
R7.1-7.2 MedWatch 404356 (2 pp.)
R8.1-8.2 MedWatch 395849 (2 pp.)
R9.1-9.2 MedWatch 385272 (2 pp.)
R10.1-10.2 MedWatch 389141 (2 pp.)
R11.1-11.3 Email requests for information from Investigator Chase-Off to Kevin Cornwell dated

R12.1-12.6 FDA-483 dated 4/15/02 (6 pp.)
R13.1-13.2 FDA-483 dated 6/8/01 (2 pp.)
R14.1-14.4 FDA-483 dated 7/27/95 (4 pp.)
R15.1-15.4 Inspectional Guidance (4 pp.)
R16.I-16.2 UTMD's response to FDA-483, Item 2 (4/15/02)

Ricki A. Chase-Off, Investigator

Karen A. Coleman, Investigator