SUMMARY

This was a limited, follow up inspection, QSIT Level III, conducted at the request of Denver District Compliance, FACTS Assignment number 275151. The inspection was conducted in accordance with C.P. 7382.845, Inspection of Medical Device Manufacturers. The firm manufactures various Class II products for labor and delivery obstetrics, neonatal intensive care, blood pressure monitoring, gynecology, urology and electrosurgery.

The previous inspection of this firm was a Level I abbreviated inspection that covered Corrective and Preventive Actions and Production and Process Controls. The inspection was conducted 6/4-6/8/01. The inspection noted deficiencies in corrective and preventive actions; device history records; process validation; non-conforming material records; electronic records and signatures; and, sampling plans. A Warning Letter was issued to the firm on 9/4/01.

A meeting was held by DEN-DO Compliance with firm management on 12/21/01 to discuss the firm's compliance issues. In response to that meeting, the firm's President, Mr. Kevin Cornwell requested that the Warning Letter be rescinded.

DEN-DO Compliance responded that the Warning Letter would not be rescinded. DEN-DO Compliance reminded Mr. Cornwell that the Warning Letter requested the firm to hire an outside consultant to audit the firm, to ensure it was operating in a state of control.

Prior inspectional history includes a Warning Letter issued to the firm on 8/15/95. The follow up inspection to that Warning Letter was conducted 9/11-9/18/98 and was classified NAI; although, some specific GMP issues were discussed with firm management.

The current inspection began on 3/26/02 with the issuance of the FDA-482, Notice of Inspection to Mr. John Rex Smith (J. Smith), Quality Manager. A second FDA-482 was issued on 4/15/02, to Mr. J. Smith, to account for the presence of DEN-DO Supervisory Consumer Safety Officer, Mr. Elvin R. Smith at the close out meeting.

The inspection was concluded on 4/15/02 when a FDA-483, Inspectional Observations was issued to Mr. Kevin L. Cornwell, President and CEO of Utah Medical Products, Inc. (UTMD). A one-week lapse in inspection was encountered from 4/8-4/12/02 due to prior obligations on the part of this Investigator.

The FDA-483 Observations were discussed with Mr. Cornwell, Mr. J. Smith, Mr. Ben Shirley, Production Development Manager, and the firm's attorney, Mr. Larry Pilot of McKenna & Cuneo, L.L.P. Also present for the close out discussion was SCSO Smith.

The inspection revealed continuing deficiencies in the following areas: process validation; corrective and preventive actions; device history records; collection and review of quality data; use of statistics; document control; internal audits; and electronic records.

Documentary sample, DOC 156363 was collected to demonstrate interstate commerce. On the advice of counsel, Mr. Cornwell did not listen to, review, or sign the Affidavit associated with this sample.

No refusals were encountered.

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

HISTORY/BUSINESS OPERATIONS/IS COMMERCE/JURISDICTION

Utah Medical Products, Inc. (UTMD) was incorporated in the State of Utah in 1978. The firm is publicly traded on NASDAQ. A copy of the 2001 annual report was requested; however, Mr. John R. Smith (J. Smith), Quality Manager and Management Representative, stated that the report was not available at the time of inspection.

I confirmed with Mr. J. Smith that the Corporate Officers include: Mr. Kevin L. Cornwell, President and Secretary; Mr. Paul O. Richins, Vice President and Chief Administrative Officer; Mr. Greg A. LeClaire, Chief Financial Officer and, Mr. Mark A. Lanman, Vice President of Sales.

Annual sales of UTMD products are approximately X X Approximately X of the finished devices are distributed in interstate commerce. UTMD is currently registered with FDA as a medical device manufacturer.

X X X X X

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Responsible individuals present during the inspection were as follows:

Mr. Kevin L. Cornwell – President and CEO
Mr. John R. Smith – Quality Manager
Mr. Ben Shirley – Product Development Manager
Mr. Larry Pilot – Legal Counsel

The Utah facility consists of a [redacted] square foot building housing [redacted] There are approximately [redacted] employees in [redacted]

The office hours are from 7:00 a.m. – 5:00 p.m., Monday-Friday. The [redacted]

The firm manufacturers various Class II products for labor and delivery obstetrics, neonatal intensive care, blood pressure monitoring, gynecology, urology and electrosurgery.

These products include: Fetal Monitoring/Intrauterine Pressure Catheters (IUP); Vacuum Assisted Deliver systems/Vacuum Pump and Silicone Cups; Umbilical Cord Management/Umbilicup and Cordguard; Disposable Pressure Transducer and Blood Sampling Systems for Critical Care Monitoring/Deltran product line; Electrosurgical generators/Finesse line; Gynecology Electrodes/C-LETZ Conization Electrodes and Utah Loop Electrodes; Neonatal and Pediatric Intensive Care/Umbili-Cath, Catheterization Tray, Nutri-Cath, Myelo-Nate, Uri-Cath, Picc-Nate, Hemo-Nate, Dialy-Nate, Thora-Cath, Pala-Nate and Disposa-Hood; Endometrial Suction Curette/Endocurette; Lumin Uterine Manipulator; Physician Controlled Irrigation/Pathfinder Plus-Bulb Irrigator; and, Pelvic Floor Stimulation/Liberty Line.

Mr. Cornwell characterized the IUP line of products specifically, as being used in high-risk deliveries, to make life and death decisions. Promotional materials for the IUP line supports that the devices are used in high-risk births (Exhibits 1B-1C).

The firm's product catalogs and promotional materials are attached as Exhibits 1A-1TT. Product labels are attached as Exhibits 69A-69D.

A review of the SLC-RP files revealed that the earliest inspection of record was conducted in 1987; however, no EIR was available in the SLC-RP files for review.

The earliest inspection on record, for which documentation was present, pertained to an inspection conducted 7/18-7/27/95. The inspection of 1995 covered the manufacture of the Class II, Intran IUP-400, Intrauterine Pressure Catheter.
The 1995 inspection revealed that the firm was manufacturing devices that did not meet performance specifications; failure investigations were not always performed; there were no procedures for manufacturing mold injected parts; and, mold injection operations had not been validated.

GMP areas including, sterility, calibration, change control and environmental control were not evaluated at that time.

On 8/4/95, UTMD responded to the FDA-483 observations, in writing to Mr. Gary Dean, Director of Compliance, Denver District. The response was found to be inadequate and a Warning Letter was issued on 8/15/95.

An inspection was conducted 9/11-9/16/98 as a follow up to the Warning Letter of 8/95. Additionally, the inspection was conducted in response to a request by CDRH to determine the cause of adverse events associated with the firm's IUP-400 device and IUP line.

At the time of the inspection, a review of the OSCAR database revealed [redacted] events that were reported industry wide for this type of product (Intrauterine Pressure Catheters). [redacted] of these adverse events involved Utah Medical IUPs, including [redacted] deaths and [redacted] injury in [redacted] deaths and [redacted] injuries from [redacted]. The UTMD devices involved included the IUP-100, IUP-200 and IUP-400 models. No deaths had been reported for devices manufactured by other firms.

The 1998 inspection revealed no significant deficiencies observed by the investigator, and no FDA-483 was issued. However, a few specific GMP issues were discussed with the firm's management, including the inability of the firm's software to track and trend similar complaint information; not following prescribed sampling plans; out of date Q/A procedures; and, inadequate purchasing control procedure. The inspection was classified NAI.

An inspection was conducted 6/4-6/8/01. This was a limited QSIT Level I inspection, which included a review of the firm's CAPA system and Production and Process Controls. The inspection focused on the Intran IUP-400 device because it had received approximately [redacted] of the firm's complaints from [redacted]. The inspection revealed new and continuing deviations from the CGMP/QS regulation.

Observations noted on the FDA-483 included, not collecting and analyzing all quality data; not taking corrective actions for problems identified through trending

reports; test specifications in the DHR that did not match those approved in the DMR; no documented evidence that in process testing was being performed; not identifying and documenting all rejects; no validation studies for the overmold primer application process; incomplete investigations of non-conforming materials; not following the non-conforming materials procedure; no explanation for using non-conforming materials; no certification for the use of electronic signatures; no procedures for the validation of electronic records; and, no statistical rationale for the use of sampling plans.

UTMD responded to the issuance of the FDA-483, in writing, dated 6/27/01. The response was found to be inadequate. The inspection was classified OAI and a Warning Letter was issued to the firm on 9/4/01. In that Warning Letter, it was recommended to the firm that a consultant be hired to certify the firm's compliance.

UTMD responded to the Warning Letter on 9/26/02. In that response, UTMD requested a meeting to discuss compliance issues.

On 12/21/01, Mr. Cornwell, Mr. J. Smith and Mr. Pilot, Legal Counsel, met with DEN-DO Compliance Officer, Ms. Regina A. Barrell and Director of Compliance, Mr. Howard Manresa. During this meeting, firm personnel were again encouraged to hire a consultant to assist them with compliance issues.

On 12/28/01, Mr. Cornwell sent a letter to Ms. Barrell requesting that the Warning Letter of 9/4/01 be rescinded. Further, Mr. Cornwell stated that he believed UTMD was in compliance with the QSR, ISO 9001 and EN 46001.

In response to Mr. Cornwell's 12/28/01 letter, a letter dated 1/3/02 was sent to Mr. Cornwell from Ms. Barrell. Ms. Barrell informed Mr. Cornwell that reinspection would be forth coming and that the Warning Letter of 9/4/01 would not be rescinded. Again, Mr. Cornwell was encouraged to hire a consultant to certify the firm's compliance with the QSR.

The current inspection was conducted at the request of DEN-DO Compliance and consisted of a limited, follow up inspection to the Warning Letter of 9/4/02. Because this inspection was a follow up, the same device was examined in an attempt to verify corrective actions taken since the inspection of 6/2001.

New and continuing deviations form the CGMP/QSR were observed during the current inspection. See Objectionable Conditions and Discussion with Management section of this report for complete details of those deviations.

RESPONSIBILITY

On 3/26/02, credentials were shown and a FDA-482, Notice of Inspection was issued to Mr. John Rex Smith (J. Smith), Quality Manager and designated Management Representative. I attempted to issue the FDA-482 to Mr. Kevin Cornwell, President and CEO. Mr. J. Smith informed me that he was the Management Representative and that the FDA-482 should be issued to him.

A second FDA-482 was issued to Mr. J. Smith on 4/15/02 to include the presence of DEN-DO SCSO Mr. Elvin R. Smith (E. Smith) at the close out meeting.

Mr. J. Smith was my contact for this inspection. Documentation collected and presented as exhibits to this report were received from Mr. J. Smith, unless otherwise noted.

Mr. Cornwell, President and CEO of the firm did not routinely participate in the inspection, in that he did not provide documentation or answer my questions directly. Mr. Cornwell and I met each evening, with the exception of the first, to discuss the day's events, concerns and observations.

Mr. J. Smith identified the corporate officers as being the same as those noted during the inspection of 6/2001. Those officers include, Mr. Kevin L. Cornwell, President and Secretary; Mr. Paul O. Richins, Vice President and Chief Administrative Officer; Mr. Greg A. LeClaire, Chief Financial Officer and, Mr. Mark A. Lanman, Vice President of Sales.

Mr. J. Smith identified Mr. Cornwell as the Management with Executive Responsibility. Mr. Cornwell is ultimately responsible for the activities of the firm.

Mr. J. Smith has been delegated the responsibility of quality assurance including GMP compliance since ><>< Prior to becoming the Quality Manager, he worked >< >< for the firm as a >< >< ><

Duties assigned to Mr. J. Smith include, management review, complaint and failure investigations, MDRs, corrective and preventive action system, document control, non-conforming materials, internal audits and 510(k) submissions. Additionally, Mr. J. Smith is in charge of the Quality Group. Further, Mr. J. Smith is responsible for the compliance activities of the facilities in Oregon and Ireland. Mr. J. Smith reports directly to Mr. Cornwell.

Some of Mr. J. Smith's duties had been assigned to >< >< >< , Quality Supervisor. >< >< is no longer with the firm and Mr. J. Smith has assumed her duties, which are listed above. The date of >< >< separation from the firm is unknown.

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Mr. J. Smith and Mr. Cornwell stated that it is UTMD's policy

Mr. Cornwell stated during several of the daily close out meetings that he is the individual responsible for the firm's performance. He admitted he is responsible for reviewing complaint trends, signing off on MDRs and for writing instructions for use and trouble shooting manuals for devices. Mr. Cornwell also stated that he is accountable to the shareholders for ensuring profits. Mr. Cornwell stated that he has degrees in

Mr. Cornwell was present at the issuance of the FDA-483 and accepted the FDA-483 as the most responsible individual at the firm. Also present for the discussion of the FDA-483 was Mr. J. Smith, Quality Manger and Mr. Ben Shirley, Product Development Manager.

Mr. Shirley is responsible for design control and reports directly to Mr. Cornwell. Mr. Cornwell identified Mr. Shirley as having a
This was the first meeting with Mr. Shirley and his duties and responsibilities beyond that of design control are unknown.

Further, Mr. Larry Pilot, Attorney of McKenna & Cuneo, L.L.P. was present via teleconference and was officially representing the firm in discussion of the FDA-483 items. Mr. Pilot may be contacted at 202-496-7561, 1900 K Street, N.W., Washington, D.C. 20006-1108, larry_pilot@mckennacuneo.com.

A copy of the 2001 Annual Report was requested; however, Mr. J. Smith stated that report was not available at the time of inspection.

There are no labeling agreements at this firm.

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

MANUFACTURING/DESIGN OPERATIONS

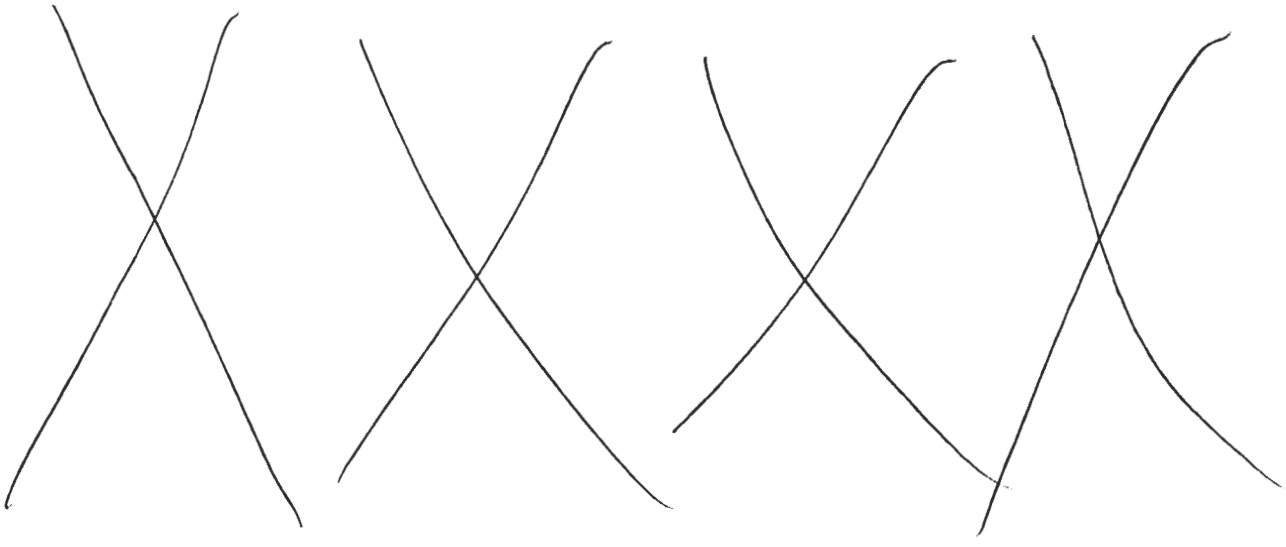
The facility consists of a I in a business park in Midvale, Utah. The facility includes a reception/office area at

the front of the building with the [illegible] area at the rear of the building. [illegible]

The firm manufactures a variety of Class II medical devices for use in the areas of delivery/obstetrics, neonatal intensive care, gynecology/urology/electrosurgery and blood pressure monitoring.

Mr. J. Smith stated that there had been no changes to operations or equipment since the inspection of 6/2001. The manufacturing areas are [illegible] The manufacturing areas are as follows:

[illegible]



In the past, UTMD used [illegible] methods for their devices. According to Mr. J. Smith, all [illegible] All sterile devices now undergo [illegible]

COMPLAINTS

Since the previous inspection of 6/2001, the firm has reported three MDRs (Attachments 1A-C). Each of the MDRs relates to the Umbilicath, umbilical catheter. In no case did UTMD relate the MDR events to quality issues surrounding the devices. The MDRs were appropriately reported, in that they

were related to a patient injury and should have been reported. However, the firm's failure investigation of the devices was not evaluated by this Investigator to determine if the firm established the relationship between the injury and the device.

There was one voluntary MedWatch filed for the Intrauterine Pressure Catheter, IUP-400. The MedWatch alleged that the IUP-400 device cracked while in the patient. There was no patient harm identified by the reporting hospital. However, hospital personnel reported that they believed that a scratch found on the infant at the time of delivery was attributable to the broken device (Exhibit 10.18).
Investigation by the firm determined that the MedWatch event did not constitute an MDR because no serious injury had been proven to be attributable to the broken device. An MDR was not filed by UTMD regarding this incident.

The firm has not initiated any product recalls since the previous inspection.

OBJECTIONABLE CONDITIONS AND DISCUSSION WITH MANAGEMENT

On 4/15/02 a FDA-483, Inspectional Observations was issued to Mr. Kevin L. Cornwell, President and CEO of Utah Medical Products, Inc. Mr. Cornwell had previously identified himself as the member of Management with Executive responsibility.

Individuals present for the discussion of the FDA-483 included, Mr. Cornwell, Mr. John R. Smith (J. Smith), Quality Manager/Management Representative, Mr. Ben Shirley, Product Development Manager and Mr. Larry Pilot, Legal Counsel via teleconference.

Also present for the presentation of the FDA-483 were Mr. Elvin R. Smith (E. Smith) Supervisory Consumer Safety Officer Denver District, and myself.

The narrative, which follows, is an account of the events surrounding the issuance and discussion of the FDA-483 observations.

It should be noted that the close out discussion occurred over an approximate five-hour period, extending from approximately 1:45 p.m. to 6:30 p.m. on 4/15/02.

The contents of the close out meeting were tape recorded by Mr. Cornwell on advice of counsel, Mr. Pilot. As I was given no advanced notice of the firm's intentions to tape the conversations, Mr. E. Smith requested that a duplicate copy of the recordings be provided to FDA. Those audio tapes, provided by the firm on 4/16/02, are included as Exhibit 70 to this EIR.

Quotations from conversations on those tapes may be included in the discussion items surrounding the FDA-483 observations. When referred to, the quotations will be identified by the location on the original tapes where the statement may be found. The contents of the tapes have not been fully transcribed by FDA.

On 4/15/02 at approximately 1:00 p.m. Mr. E. Smith and myself arrived at Utah Medical Products, Inc. (UTMD) to conduct close out discussions with the firm's Management.

Mr. J. Smith greeted Mr. E. Smith and myself. I explained to Mr. J. Smith that I needed to issue a new FDA-482, Notice of Inspection to account for the presence of Mr. E. Smith at the inspection. A FDA-482 was issued to Mr. J. Smith.
Mr. J. Smith asked if I had a FDA-483 to issue. I stated that I did. Mr. J. Smith asked for copies of the FDA-483 so that each participant in the close out meeting would have a copy to review.

I provided two unsigned copies of the FDA-483 to Mr. J. Smith. I explained to Mr. Smith that they were not official copies, as they were not signed. I also told him that I would be requesting the unsigned copies back at the end of the discussions therefore, any notes made by the firm would need to be made on a separate piece of paper.

With that said, Mr. J. Smith stated that he was going to gather people together for the close out meeting and that it could take some time. Mr. J. Smith then left Mr. E. Smith and I alone in the small conference room for approximately 30 minutes.

Mr. J. Smith returned to state that firm personnel were ready to conduct the close out meeting. We gathered in the upstairs, large conference room.

Mr. Cornwell greeted Mr. E. Smith and me. Mr. E. Smith introduced himself to the firm's management. Mr. E. Smith and I were introduced to Mr. Ben Shirley.

Mr. Shirley identified himself as the Product Development Manager. I asked Mr. Shirley what his duties included and he stated that he was involved in Design Control and the quality aspects of design.

Mr. Cornwell informed us that he would be recording the close out meeting on audio tape, on the advice of Legal Counsel. Mr. E. Smith told Mr. Cornwell that in situations such as this FDA makes their own recording of the discussions; however, we would accept a copy of the firm's recording if one would be made readily available. Mr. Cornwell agreed to provide a copy of the tapes in a timely manner.

Once the tape recording equipment was set up, Mr. Cornwell then informed Mr. E. Smith and me that the firm's Legal Counsel, Mr. Pilot would be participating in the close out via teleconference. Mr. Pilot was telephoned and placed on speaker. The tape recorder was started and the close out meeting began at approximately 1:45 p.m., as is identified on Tape 1, Side 1 (Exhibit 70).

NOTE: In duplicating the tape recordings to be provided to CDRH and SLC-RP, the tapes went from a set of three taped originals, provided by the firm, to a set of five taped copies. This is due to the difference in tape length between the originals and the copies (45 min/side vs. 30 min/side). Further, the condition of the tapes provided by the firm is extremely poor. While conversations can be discerned, the voices on the tape are distorted.

The following section of comments can be heard on Tape 1, Side 1 (Exhibit 70)

Mr. Cornwell began the discussions by introducing the participants for identification on the tape.

After initial introductions and comments, Mr. Pilot wanted to know why Mr. E. Smith's name was on the FDA-483. Mr. E. Smith's name was typed on the FDA-483 but there were no signatures. The original intent was to annotate the FDA-483 at the end of the document, prior to signing it, to indicate that Mr. E. Smith was only present for the close out meeting and did not make any direct observations as identified on the FDA-483.

However, at Mr. Pilot's immediate objection, it was agreed that Mr. Smith's name probably should not have been included at all on the FDA-483, and was therefore, lined out, initialed and dated by this Investigator.

Mr. Pilot then asked if any of the FDA-483 Observations applied to Section 704(b) of the Act (FD&C Act). I responded that my Observations were those things that I consider to be violations of Good Manufacturing Practices as they apply to medical devices.

Mr. Pilot asked if the Observations were my opinion. I replied that of course my Observations were my opinion in that, it is my job to make a decision as to how things (operations, processes, and documentation) either are or are not in compliance with the GMPs for medical devices.

Mr. Pilot pressed for an answer as to whether or not the Observations related to 704(b). I emphasized that I could not prove that the devices were "contaminated" as is stated in 704(b); however, Observations noted including Observation 1 (see

below), goes to sterilization validation. Therefore, I also could not be sure that devices were not contaminated.

NOTE: It should be noted that the FDA-483 states that observations should be reported pursuant to Section 704(b) or to assist firms in complying with the Acts and regulations enforced by FDA.

The *Investigations Operation Manual 2002* (IOM), Section 512.1 Reportable Observations states to include specific factual observations of, "6. Observations of faulty manufacturing, processing, packaging, or holding, of food, drug, or device products as related to current good manufacturing process regulations including inadequate or faulty record keeping."

Regarding my Observations, Mr. Pilot was emphasizing my use of the term violation. As explained above, I stated that it was my job to try and decide how the firm's practices either are or are not in compliance with the device GMPs and to document through Observations potential non-compliance.

However, the IOM Section 516 instructs the investigator to inform firm personnel that, "the conditions listed may, after further review by the Agency, be considered to be violations of the Food, Drug and Cosmetic Act."

As will be described at the end of the close out discussion, I explained to all present that I do not have the responsibility for making a decision regarding any action taken by the Agency in response to this inspection or the Observations listed. Further, that DEN-DO Compliance as well as CDRH evaluates the Observations before any action, if any, is decided upon.

Additionally, during the close out discussions, Mr. E. Smith reiterated to all present that the Observations are the Investigator's opinion of deviations related to the QSR.

Finally, in the final close out discussions, I again stated to all present that the Observations were my findings of deviations from the QSR, and that Compliance, CDRH and GC will make the decision on what those Observations represent.

Mr. Pilot asked if a Supervisor had reviewed the Observations. Mr. E. Smith stated that he is a Supervisor and had reviewed the Observations noted on the FDA-483.

Mr. Pilot wanted to know if Mr. E. Smith had reviewed my Observations with anyone from headquarters. Mr. E. Smith stated that it was not a requirement to get approval from headquarters for the issuance of a FDA-483.

Mr. Pilot questioned the inclusion of the preamble to the FDA-483, as required by C.P. 7382.845, which states, "The observations noted in this FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the GMP regulation."

Mr. Pilot wanted to know, where, precisely, it was stated in the GMP regulation that the firm is, "responsible for conducting internal self-audits to identify and correct any and all violations of the GMP regulation." (Underline added for emphasis)

Mr. Pilot requested that I strike the statement from, "...to identify and correct any and all violations of the GMP regulation."

I informed Mr. Pilot that I would not be striking any of the statement, as it is FDA's agency policy that the statement is to be included on all FDA-483s related to medical devices.

I explained to all present, my method for conducting the close out discussions of the FDA-483 items. I read the preamble to Mr. Cornwell and explained that I did not cover all aspects of the firm's operations during my inspection. I asked if Mr. Cornwell had any questions regarding the preamble. He stated that he might not agree that the Observations were violations of the GMP (as implied by the preamble statement). We agreed to move into the discussion of the FDA-483 Observations.

NOTE: This was a follow up inspection conducted in response to a Warning Letter issued in 9/2001 after an OAI inspection conducted 6/2001. The previous inspection focused on the Intrauterine Pressure line of devices. Therefore, in reviewing corrective actions, I again focused on the IUP line to verify the objectionable conditions from 6/2001 had been adequately addressed. See EIR section "Voluntary Corrections".

FD-483 ITEM 1.1 - In XXX the IUP line of devices underwent a change in catheter material from XXXXXX alidation review revealed the following:

A. There are no raw test data or a validation protocol for the XX sterilization, which was approved for the devices;
B. There are no raw test data or a validation protocol for the X sterilization, which was approved for the device;

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C. There is no evidence to support the five-year expiration date given to the devices.

FD-483 ITEM 1.2 - In [redacted] the IUP product line was approved for a [redacted] sterilization per [redacted]; however,

A. There are no raw test data or a validation protocol for a [redacted] sterilization and,
B. The testing of the catheters after the [redacted] sterilization did not include tests of the physical integrity of the devices (i.e. tensile strength of the plastic catheter, inspection for discoloration or abnormalities in the catheter plastic), The only tests performed were functional/electrical evaluation tests.
C. There is no statistical rationale for the number of devices [redacted] selected for the tests that were performed.

FD-483 ITEM 1.3 - A Memo dated [redacted] states that the IUP line of devices underwent [redacted]; however, the test results do not indicate:

A. How the devices were sterilized prior to the testing;
B. How many devices were evaluated.

FD-483 ITEM 1.4 - In [redacted], the firm switched from [redacted] There is no evidence that an [redacted] sterilization validation of the IUP device in a [redacted] was ever completed.

DISCUSSION OF ITEMS 1.1-1.4

Background for Observations

A review of the firm's complaints was conducted. I requested and received a Complaint Listing Report for the period of June 2001 (date of previous inspection) through March 2002 (date of current inspection) (Exhibit 2).

Examination of the complaints revealed that UTMD received [redacted] complaints regarding the cracking of Intrauterine Pressure Catheters (IUPs) from 6/2001-3/2002.

I reviewed the following complaints regarding cracked catheters: [redacted] was inadvertently not collected.)

[redacted]

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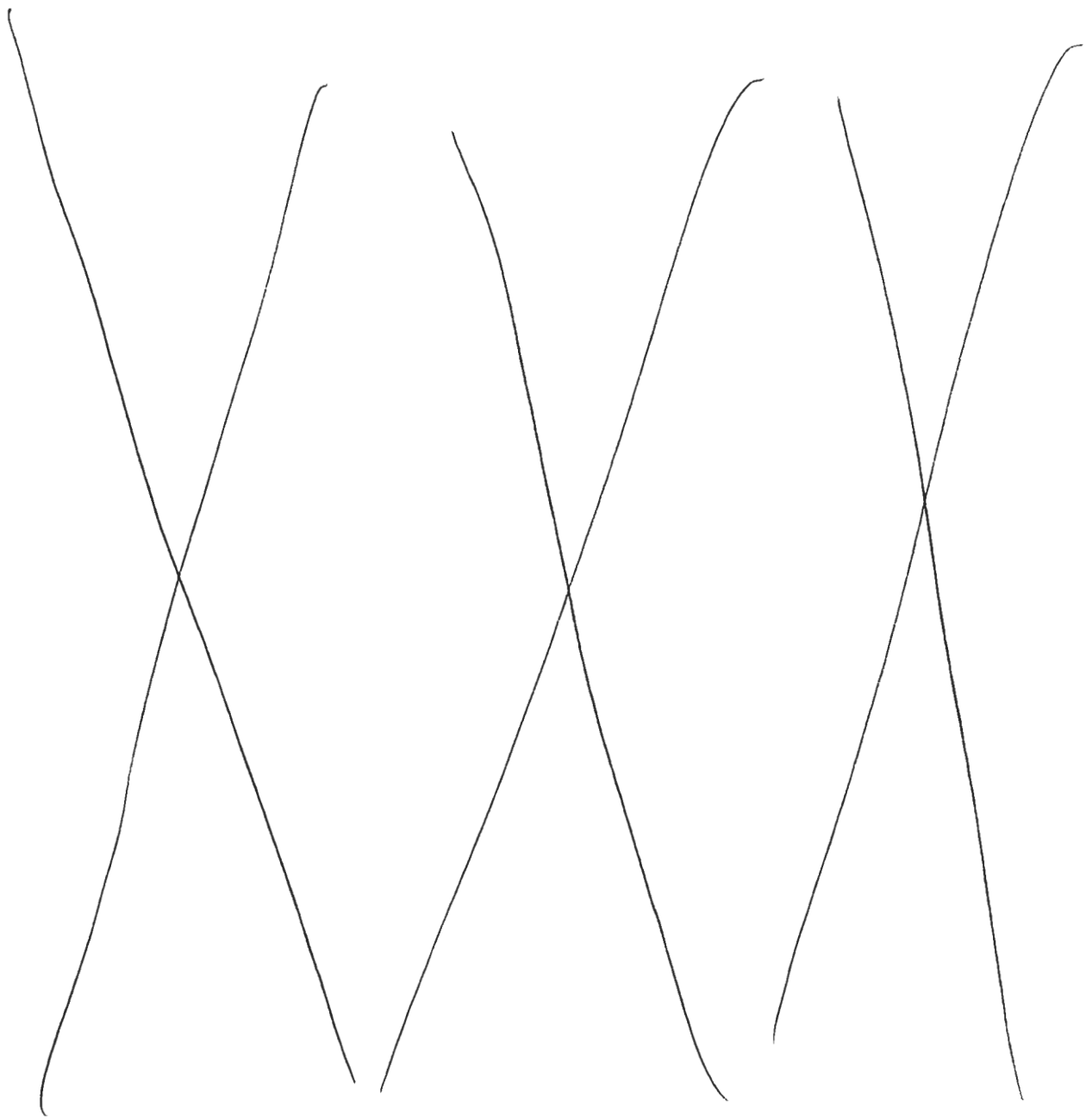
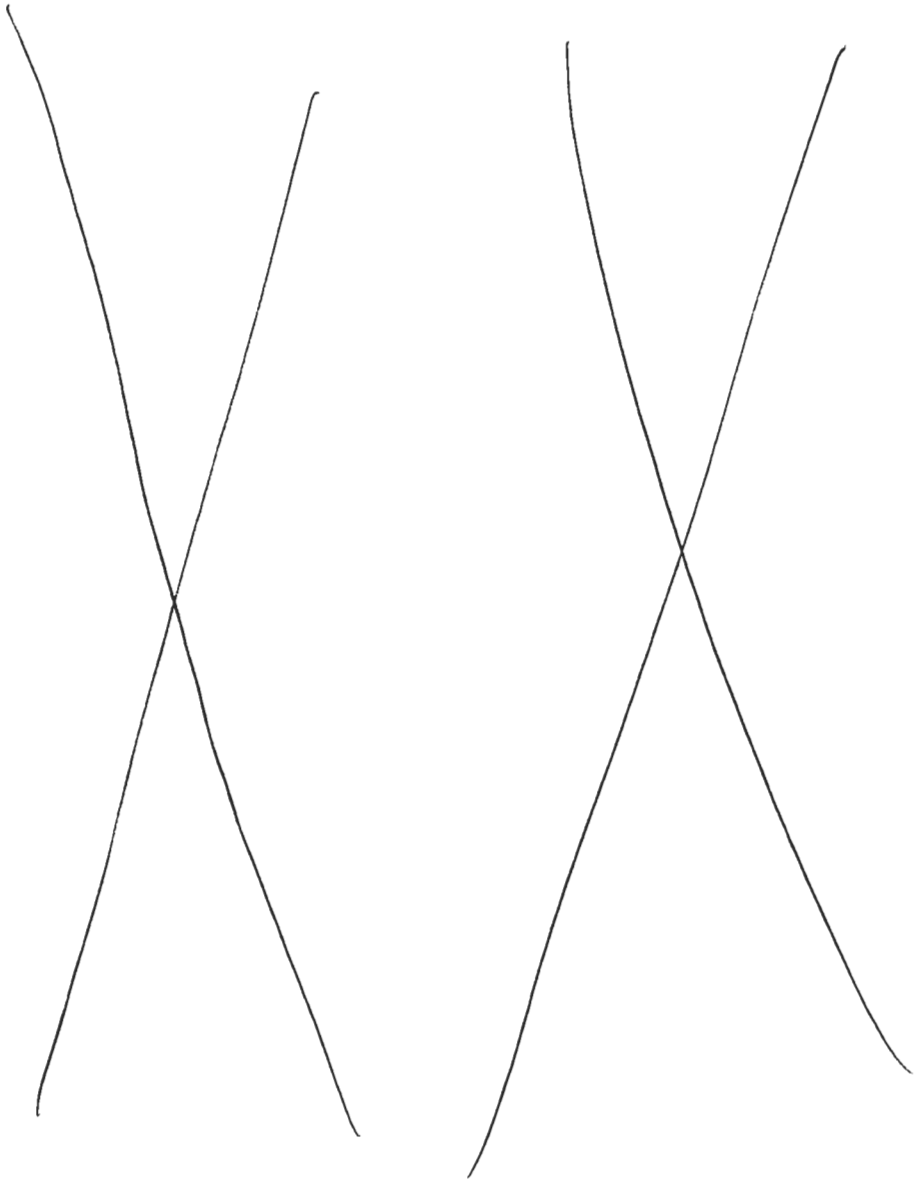
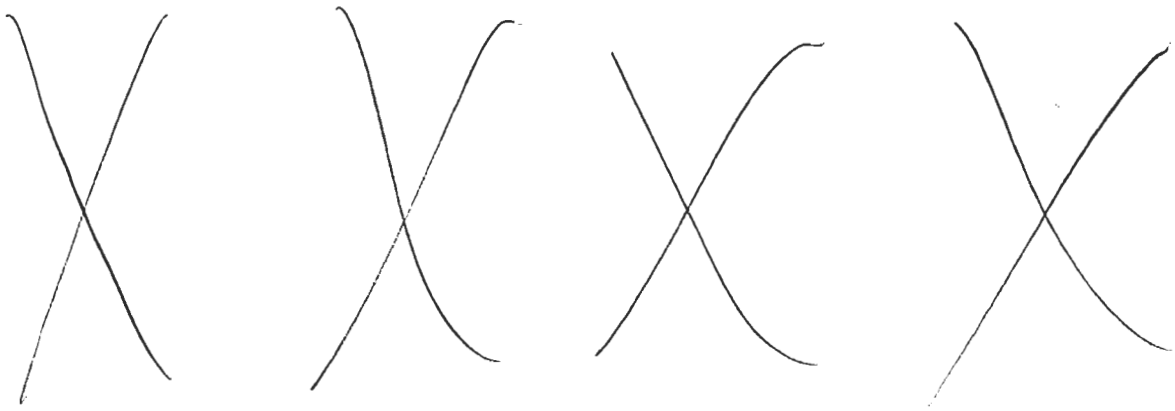




For all of the complaints filed above the conclusion was reached that the complaints were not MDR reportable because although the product had malfunctioned, there was no potential harm should the malfunction recur.

A Memo dated analyzes the complaints regarding catheter cracking . Note that the date of the Memo is and does not include those complaints or data received beyond that date. This Memo confirms that no MDRs were reported as a result of these complaints (Exhibit 15).

The firm's Risk Analysis (FMECA) for the IUP line of devices did not consider the cracking of the catheter lumen as a risk factor associated with these devices (Exhibit 16.3-16.5).



The decision was made in to switch from . At the same time a project was undertaken to switch the devices from . The change in the was not approved until . In the interim, devices continued to be and packaged in the . (See complaint reports referenced above).

Discussion Directed Toward Observation 1.1

NOTE: UTMD uses the word "Qualification" when discussing sterilization in documents. In the following section, I use the term Qualification where the firm has used that word in documents. I use the word Validation to describe processes, which should be validated as defined in 21 C.F.R. 820.

Due to the history of complaints regarding catheter cracking I chose to investigate the firm's history of this device, particularly the changes made to the device and its associated processes since
As previously stated, in UTMD made a materials change to the IUP line of catheters. Catheters were originally approved for manufacture from
. However, , the manufacturer of

Sterilization of the devices made from the new material should have been validated, unless an equivalency between the old and the new materials had been established. There was no documentation establishing such equivalency.

I knew from reviewing the complaints that the catheters had been approved by UTMD for sterilization. I asked Mr. J. Smith to provide evidence of the sterilization (process) validation for as it related to the IUP line of devices.

Mr. J. Smith stated that it (the validation) was a long time ago. I told him that I realized that but, the complaints revealed a connection to the sterilization of the device and I wanted to evaluate the sterilization validation.

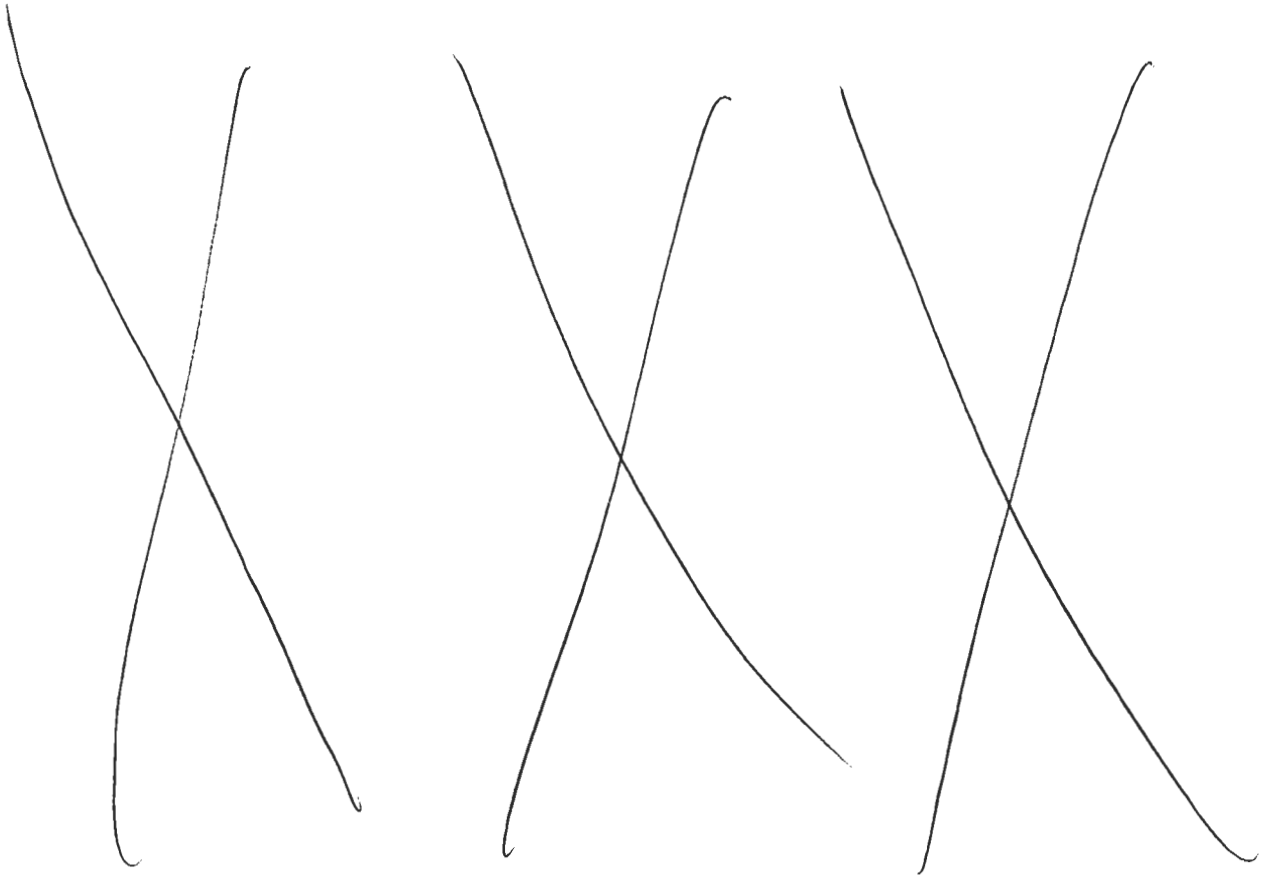
Mr. J. Smith provided , 3-4 inch binders which contained the original design specifications for the IUP line of devices, dating as far back as I reviewed the notebooks several times and did not find the sterilization validation documentation relating the to the change in materials.

I told Mr. J. Smith that I was looking for the validation protocols and the raw data, reviewed by the firm's personnel, to support the acceptance of sterilization for the IUP line of devices constructed from

Mr. J. Smith provided a project book containing a copy of
Additionally, Mr. J. Smith provided

Mr. J. Smith identified the Test Protocol and the Test Report as containing the sterilization validation information I was requesting.

A review of the Test Protocol revealed that between



I asked to see the sterilization qualification/validation protocol and raw data [illegible] to support the claim that qualification was indeed performed. Mr. J. Smith continued to refer to the Test Report.

The Sterilization Qualification states that the tested devices were found to be sterile at a minimum [illegible] However, the qualification does not state what the maximum exposure was for this material.

The conclusion was drawn that because the device was found to be sterile at [illegible], the same exposure limits used for the [illegible] could be applied to the [illegible] Those limits used on the [illegible] were [illegible] The qualification states that, [illegible]

There is no evidence in the Test Report, or otherwise provided, to demonstrate that the [redacted] material was [redacted] and evaluated for the effects of that exposure on the materials.

Finally, the Sterilization Qualification in this Test Report makes no mention of the devices having been qualified for [redacted] There is no protocol for [redacted] process validation and there are no raw test data from the [redacted] to indicate that [redacted] validation studies were ever undertaken. There is no evidence that the devices were tested for sterility after the process or that an evaluation of [redacted] residuals was made.
Again there was no protocol for the [redacted] qualification and there are no references made to any Standards (ANSI/AMII/ISO) that could have been used for the qualification.

The devices constructed from the new [redacted] were given a [redacted] shelf life. I asked Mr. J. Smith for evidence to support the [redacted] shelf life for the devices. Mr. Smith did not produce any test results, protocols or studies to support the [redacted] expiration date.

The Test Protocol mentions Artificial Aging of the catheters (Exhibit 17.9); however, the Test Report does not identify the devices being approved for a [redacted] expiration date. There is no evidence that real time shelf life studies were conducted. Mr. J. Smith admitted that the devices were given a [redacted] shelf life.

Beyond the Test Protocol and the Test Report, there was no evidence of validation protocols or raw test data to support the acceptance of the devices for [redacted] expiration date.

NOTE: Exhibits 18.31, back and 18.42, back, make reference to [redacted] sterilizations. Those sterilizations were conducted to determine the physical properties of the resin/device after exposure to [redacted] The cycle parameters used (i.e. preconditioning, exposure and aeration) are not defined in the Test Report. Further, the functional tests do not include validation of the sterilization cycle for a finished device made from the select material and do not mention sterility tests or residual evaluation as part of the tests that were conducted.

[redacted] wrote the Test Report. Individuals in [redacted] approved the report. The final signature was dated [redacted]

On [redacted] UTMD received a letter from FDA's Office of Device Evaluation, approving the IUP catheters for a new 510(k), K955443 (Exhibit 19). Page 12 of the documentation supporting the 510(k) contains Sterility Information (Exhibit 19.5).

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The Sterility Information states that, [redacted]) Again, there is no evidence in the Test Report or Protocol to support this claim. No other evidence was provided at the time of the inspection.

In response to the Observation 1.1 Mr. Cornwell and Mr. Pilot stated that they did not believe that there was a Regulation regarding validation (of sterilization) in [redacted]

I stated that there was a Regulation in [redacted] which spoke to process validation, though not to sterilization validation specifically.

Mr. Pilot asked if Mr. E. Smith agreed with me on that point. Mr. E. Smith stated that there was no explicit language in the regulation that used the word validation but that FDA and industry have been in agreement on the requirement for process validation.

NOTE: The current requirement for process validation can be found in 21 C.F.R. Section 820.75 Process Validation. Prior to 1996 and the QSR, the requirement for process validation was found in 21 C.F.R. Section **820.100(a)(1)** Specification Controls. (Ref. *The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices* by Kimberly A. Trautman)

A FDA Guidance Document, "Deciding When to Submit a 510(k) for a Change to an Existing Device", issued by the Office of Device Evaluation on January 10, 1997, explains the agency view on process validation and design control, according to the 1978 regulation. (Select pages have been included as Attachments 2.1-2.5)

Specifically, "The 1978 GMP regulation, however, is not entirely silent on device design. It requires manufacturers to document in the device master record (§820.181) any changes (and internal approval of changes) to device design and any associated testing (§820.100). It also requires process validation to assure that devices meeting the designed quality characteristics will consistently be produced (§820.5 and §820.100). Finally, manufacturers must have a formal approval procedure for any change in the manufacturing process of a device including those dictated by design changes (§820.100(b)(3))." (Underlining and Bold added for emphasis)

Mr. J. Smith stated that he had provided the validation information in the Test Report (Exhibit 18), which included testing of the devices after [redacted] Mr. J. Smith stated that he did not see the difference between what

was done in the Test Report and what I was asking for in process validation of [redacted]

The next objection Mr. Pilot posed was that because an [redacted] performed sterilization, then the firm, UTMD, did not have the responsibility to document the validation.

I explained that UTMD had certain responsibilities involving the sterilizatior [redacted] Those responsibilities include, defining what the manufacturer, UTMD is responsible for, such as building the devices, selecting what lot of devices would be used for validation, and how many devices would be used for validation. Further, UTMD had to come to an agreement as to what the [redacted] And, finally, UTMD had the responsibility to review the validation steps performed [redacted] decide if the [redacted] met the obligation, decide if the sterilization performed [redacted] was adequate by review of the data, then approve the validation for use at UTMD for this line of devices.

Mr. Pilot suggested that the firm may have done the validation and simply needed to get the data [redacted] However, if the data from the [redacted] was never received and reviewed by UTMD personnel, prior to the approval of the validations, then the validation review was inadequate.

Discussion Directed Toward Observation 1.2

As stated in Observation 1.1, the IUP line of devices was approved for [redacted] after the materials change to [redacted]. This is confirmed by the Introduction to Test Protocol [redacted]

The introduction states that the IUP line of devices was approved for [redacted]. If the product failed to meet post sterilization specifications, then the product was approved for [redacted]

At the time of this Qualification, [redacted], it was UTMD's practice to [redacted] devices from the sterilized lot, and to perform a Final Test on those devices. If the sample of devices failed the Final Test then all of the devices would be opened, retested and resterilized.

Further, post sterilization test included, testing the biological indicators [redacted], and sterility testing done on a sampling of lots produced.

Gamma post sterilization inspection also included reviewing the sterilizer records to make sure the sterilization cycle was complete and adequate.

When asked if devices had failed post sterilization specifications and had to be sterilized [illegible] Mr. J. Smith stated that he was not aware that this scenario had ever actually happened.

[illegible] Specifically, if the product failed to meet post sterilization specifications after the [illegible] sterilization, then failed to meet post sterilization specifications after the [illegible] sterilization, then a [illegible] would be completed.

The validation/qualification is outlined in [illegible], and the results of the protocol are recorded in Test Report, [illegible] (Exhibits 20-21).

The TP states, [illegible] The results of the functional tests are reported in the Test Report.

The validation/qualification lacks the following:

There is no definition of the type of [illegible] sterilization, [illegible] or otherwise. There is no statement as to which [illegible] performed the actual sterilization. It is known that a [illegible] must have done the sterilization, as UTMD [illegible]

The [illegible] sterilizations are based on validation that was not documented or presented as documented during the inspection. See Observation 1.1.

There is no evidence that an evaluation of the time needed for aeration after a [illegible] was conducted. More specifically, there is no evidence that the devices were evaluated for [illegible] residuals after the [illegible] exposure.

There are no raw test data from the [illegible] to demonstrate the conditions under which the devices were sterilized.

The only tests performed on the devices after this [illegible] exposure were for electrical functionality. After the initial qualification, as described by Mr. J. Smith as being outlined in Test Report, [illegible] (Exhibit 18) the devices received a much more vigorous testing.

Specifically, after the [illegible], the devices were tested for [illegible]

The tip/tubing joint is a glued section of the device, which may be affected by the moisture and heat associated with

The qualification did not test for the same parameters tested for in the initial qualification . Further, it could be expected that if a could have an effect on the device, then a exposure may also have an effect on the device. These parameters were not considered.

While a may not adversely effect plastics, there is no evidence that the interrelationship, if any, was examined between the effects of ; and, what effect those sterilizations may have on the integrity of the devices. The physical integrity of the devices was not evaluated after the exposure.

There were devices selected for this qualification. The TP does not state where the devices came from, as in which lot of product the devices were manufactured under. It is not known if the devices were manufactured under normal manufacturing procedures as part of a lot, or if they were prototypes subjected to sterilization cycles for the purpose of completing this TP. There is no documentation of the relevance of devices used in this process qualification.

The process was approved by Memo, The Memo states that (Exhibit 20) demonstrates that the IUP-400 is qualified to withstand

The IUP line of devices is currently approved for sterilization, based on the Qualifications noted in (Exhibits 17-18 & 20-21). Devices in the are qualified for ; and devices in the are qualified for (Exhibit 57.6).

UTMD's current practice does not include post sterilization functionality tests (i.e. Final Test) on a sample of devices from the sterilized lot. Exhibits 37.6, 38.6 and 40.11 document that devices are released without post sterilization Final Test being performed.

Specifically, DHRs dated as late as contained a procedure for removing final test samples, post sterilization and retain unit. That was documented on the DHRs between the steps

The current DHRs do not reflect the removal or testing of any samples post sterilization prior to release to distribution.

It is unknown when UTMD stopped performing post sterilization Final Test on a sample of X units from each lot.

Mr. J. Smith stated that the evidence I was seeking for the validation was present at the firm. However, he felt that there was a miscommunication between he and I regarding the information I was looking for. Mr. J. Smith felt that I was seeking proof of "product" validation. When what I was looking for was evidence of process validation.

I asked Mr. J. Smith several times during the inspection for the protocols and raw data to support the sterilization (process) validations for these devices. Mr. J. Smith never provided any documentation other than those Exhibits attached to this EIR.

Mr. E. Smith asked why if the documentation was available it was not presented during the inspection. Mr. J. Smith continued to state that it was a miscommunication problem.

Discussion Directed Toward Observation 1.3

In X the IUP line of devices underwent Biological Effect Testing, per FDA Memorandum G95-1. The Memorandum required Biological Effect testing to replace Tripartite testing, for 510(k) submissions dating after July 1, 1995 (Attachment 3).

The firm's 510(k) submission for the change from X X X X was submitted 11/27/95.

A Memo dated X states that testing had been completed for the Biological effect requirements (Exhibit 23). The tests were done on samples of IUP-450 X X X The samples passed all tests.

However, the Memo does not contain information for the evaluation of the testing, which was done. For example, the Memo does not state what the sample size of the tests was. Further, the Memo does not state if the devices were sterilized prior to the testing (Exhibit 23).

It is known that the IUP devices, as of a X Memo (Exhibit 22), were approved for X X X X X X X X X
There is no information in the Biological Effects Memo to indicate if the devices were sterile prior to testing and if sterile, how the devices were sterilized.

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There is no protocol for this testing.

[Tape 1, Side 2] (Exhibit 70)
Mr. Cornwell and Mr. Pilot took exception to the whole line of Observations 1.1-1.3 in that they felt they were not based on current issues.

I explained that the validations and device testing were reviewed due to the current and on-going issues of catheter cracking. I further explained that it was my intent to try to determine if the firm conducted testing and validation of the device, properly, when the device was developed, such that those validations could be eliminated as a source of cause for the current device failures.

I explained that regarding Observations 1.1-1.3 UTMD personnel continuously made statements such as the device is qualified for [redacted], and the device has passed Biological Effects testing, and has failed to produce documented evidence to support those conclusions.

(The current sterilization practices are based on the sterilization activities dating back to [redacted] Further, devices sterilized based on the work in [redacted], are still on the market.)

Mr. Cornwell asked me, what do you call [redacted] devices produced without major complaints. I explained to Mr. Cornwell that what he was proposing was called retrospective validation.

I told Mr. Cornwell that FDA seldom accepts retrospective validation because there is usually not enough documentation of processes and controls to support it.

Mr. Cornwell and Mr. Pilot held to the idea that quality is based on or related to volume of product sold.

Mr. Cornwell read the definition of Validation, which states, "Validation means confirmation by examination and provision of objective-evidence that the particular requirements for a specific intended use can be consistently fulfilled." ((21 C.F.R. 820.3 (z)).

Mr. Pilot stated that the Regulation allows for the manufacturer to decide if validation is necessary and does not dictate that a firm must validate its processes.

I explained that sterilization is a "special process" and cannot be verified by subsequent testing and does need to be validated. Mr. Pilot continued to disagree.

Mr. Cornwell continued to support his statement that having [redacted] devices on the market is validation and is objective evidence, because there have been no patient injuries related to the devices and no product liability suits.

I reminded Mr. Cornwell that a voluntary MedWatch was filed on a complaint for a catheter having broken while intrauterine (Exhibit 10), and that his characterization of no patient injury was not accurate.

I further explained that low incidence of complaints does not validate the process which we were discussing, that of sterilization.

Discussion Directed Toward Observation 1.4

In [redacted] UTMD approved a design change to the [redacted] of the IUP line of catheters from a [redacted] This change was approved under Design Control document, [redacted] Directive for the Development of Products (Exhibit 24).

What is important to note is the following:

In response to consumer complaints of cracking, UTMD made the decision in [redacted] to stop [redacted] of the IUP devices. From that point forward, the IUP devices were to be [redacted]

As is summarized in Observations 1.1-1.3 there was no evidence that an [redacted] process validation was ever completed, although the firm approved the process for use.

By the time the design project for the [redacted], there was still no evidence that the devices, [redacted] could be successfully [redacted]

Test Protocol, [redacted] and the Test Report, [redacted] (Exhibits 26 & 27) were reviewed, as was the firm's 510(k) amendment rationale (Exhibit 25).

Sterilization of the devices in the [redacted] is addressed in the [redacted] The section reads,

[redacted]

There was no evidence provided, as requested, to support any approval of the device for [redacted] on prior to this [redacted]

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The Project Manager's Checklist for New Product Development refers to [redacted] for the validation of the [redacted], As stated above, [redacted] does not speak to [redacted]

Summary of Observations 1.1-1.4

Complaints of catheter cracking began in [redacted] and continue into [redacted]. A review of the catheter complaints led to a review of the firm's history of process validation and changes to the device since [redacted] The devices underwent a change in [redacted]

There is no evidence that [redacted] validation, based on low and high dose evaluation, was undertaken. The assumption was made that the [redacted] material could withstand the same [redacted] as the previously used [redacted]). Further, there was no validation protocol or raw test data to support the [redacted] validation.

At the same time that the new material was approved for [redacted], the devices were approved for [redacted] There was no test protocol or raw data to support the [redacted] validation. There was no documentation of sterility testing or residual analysis associated with the [redacted] validation. There was no mention of [redacted] qualification in the original Test Protocol, [redacted] or Test Report, [redacted]

There is no validation protocol for either [redacted] that denotes what aspects of validation UTMD will be responsible for and what aspects the [redacted] will be responsible for.

Further, after the approval of the [redacted] material, the devices were given a [redacted] shelf life. There is no evidence that any studies were conducted to support a [redacted] shelf life for the device.

In [redacted] the devices were approved for a [redacted] There was a protocol for functional testing of the devices after a [redacted] but no sterilization process validation protocol or raw data to support the [redacted] validation and its subsequent approval.

Specifically, there was no evidence of residual testing after the [redacted] exposure (Exhibits 21 & 22).

The [redacted] was based in part on the original [redacted] validation allegedly completed in [redacted].

In [redacted], in accordance with an FDA requirement for Biological Effect testing for 501(k)s submitted after July 1, 1995, UTMD performed the required tests. However, there is no documentation to describe how the devices were sterilized prior to the tests being performed, and how many devices were evaluated in the testing (Exhibit 23).

Finally, in [redacted] the [redacted] for the IUP line of devices was changed. The [redacted] There was a comparative resistance study done on the [redacted] that demonstrated the [redacted]

However, up to [redacted], there was no evidence that a complete and adequate [redacted] had been performed for the device in the [redacted] Therefore, the comparative resistance study did not lend much evidence to the firm's conclusion that the devices could be adequately [redacted]

Currently the firm distributes the IUP line of devices in a [redacted] There was no evidence presented at the time of inspection, from [redacted] forward, to support the use of [redacted] on devices packaged in a [redacted] Supporting raw data was not provided by the firm as requested during this inspection.

The current ongoing shelf life testing is for the [redacted], not the device itself (Exhibit 27). There was no evidence presented to support the [redacted] shelf life given to the device in [redacted] or subsequently. The [redacted] shelf life for the device in the [redacted] remains in effect per the Device Master Record (DMR). (Exhibit 57)

The Bioeffects testing did not state if the device was sterile prior to testing. If the device was sterilized by [redacted], then the Bioeffects testing does not address the current method of sterilization being used by the firm.

The firm continued to [redacted] IUP devices in the original [redacted] until [redacted] With a five-year shelf life, devices could remain on the market until [redacted].

UTMD's complaints stated that the firm switched to the [redacted] However, the firm did not approve the qualification for the [redacted] (Exhibit 27)

The firm has received complaints of [redacted] devices, in the [redacted], that have been returned for cracking. Again, with a five-year shelf life, the devices, [redacted] could remain on the market until [redacted]

From [redacted] there were approximately [redacted] devices manufactured.

I asked Mr. J. Smith if the firm gave any consideration to a product recall for these events. Mr. J. Smith stated that the occurrences were low level and that corrective action had been taken.

There have been no notifications made to user facilities regarding the condition of the devices or their potential failure. There has never been a warning on the product labeling to store the devices in [redacted] conditions. (Labeling is included for IUP devices, as Exhibits 69A.6-69A.13)

NOTE: Post-inspectional review of the DMR shows that [redacted] is still an approved sterilization process for IUP devices and that the [redacted] is still an approved packaging material (Exhibit 57.6).

[redacted]

However, the current DMR dated [redacted] still allows for the use of [redacted] in manufacturing the IUP line of devices (Exhibit 57).

FD-483 ITEM 2 - Corrective/Preventive Action Report (CPAR) [redacted] was opened on [redacted] and closed on [redacted] to address complaints of Intran (IUP) catheters, which had cracked lumens. A review of CPAR [redacted] revealed that,

[redacted]

DISCUSSION OF ITEMS 2A-C.

CPAR [redacted] was opened on [redacted]

The CPAR was closed on [redacted]

There is no documentation that the Corrective and Preventive action considered the effects of the device failure or potential failure on the patient. There was no risk analysis performed in deciding if the device failures posed harm to the patient or the fetus. Complaints have been received of devices cracking while intrauterine (Exhibits 10 & 5) and one voluntary MedWatch was filed by a user facility (Exhibit 10).

UTMD identified a source of the device failure as [redacted] There was no notification to user facilities that [redacted] of the device could lead to failure. Further, there are no instructions on the labeling for preventing [redacted] of the device (Exhibit 69A.6-69A.13).

The CPAR [redacted] stated that there had been no reported complaints of cracking catheters that had been [redacted] It further stated that complaints would be monitored and if [redacted] related cracking occurred a new CPAR would be opened.

[redacted] complaints of [redacted] cracking occurred on [redacted] These complaints involved [redacted] units returned due to cracking. Each of the units was [redacted] (See Discussion of Observation 1.4)

Although these complaints occurred, no subsequent CPAR was opened to address the issues, as stated in CPAR [redacted]

Finally, CPAR did not address how these failures may have affected other devices manufactured by the firm. There is no documentation that the firm considered whether or not there were devices manufactured of similar materials [redacted], sterilized in a similar manner [redacted] and packaged in a similar way [redacted] that may experience the same types of failures of the IUP line.

I asked Mr. J. Smith if the firm manufactured any similar devices to the IUP, which could be affected by the findings of this CPAR. Mr. J. Smith stated that he did not think there were. It is still unknown to this Investigator whether or not similar devices exist.

It is known from complaint tracking records that [redacted] have also had complaints of cracking (Exhibits 30). It is not known if those complaints are in anyway related to the same type of cracking seen in IUP devices.

Regarding the review of the CPAR in deciding the effects of device failure on patients, Mr. Cornwell stated that the firm did conduct meetings to determine if there was an effect on patients.

During the inspection I asked Mr. J. Smith for documentation to demonstrate that someone in management was aware of the complaints and made a decision that these failures, in totality, would not adversely effect a patient. No documentation was provided.

Mr. Pilot stated that the firm might not have a requirement to document the decisions made by Management. He further stated that the fact that Mr. Cornwell stated that the meetings and discussions occurred, was a representation from the firm that should be accepted from the company unless I believed that the statement was false. Mr. Pilot's opinion was that the firm did not have to document the decision that the failed device would not effect the patient.

NOTE: UTMD's Quality Assurance Procedure, "Customer Complaint System", QC-GE-10, states that, [redacted]

There were no meeting minutes or other documentation provided to support Mr. Cornwell's statement that management evaluated the effects of the device failure on patients, either in the individual complaints I reviewed or in CPAR [redacted]

Mr. E. Smith explained to Mr. Pilot that there needed to be evidentiary documentation to support the firm's claims that processes were followed and events occurred.

Mr. Pilot stated that it should be taken on good faith that the firm is telling the truth or it must be demonstrated in litigation that I (FDA) had been lied to.

Mr. E. Smith pointed out that the Regulation states that complaint files shall be maintained and one cannot maintain a verbal statement.

Mr. Pilot continued to object stating that the FDA-483 Observations were nothing more than the Investigator's opinion.

Mr. E Smith stated that the FDA-483 is a list of observations that in the opinion of the Investigator reflect or identify objectionable conditions with respect to the CFR.

Mr. Pilot again addressed my use of the term "violations" and stated that the Observations were violations as I stated in my opening comments. That issue has been addressed previously in this EIR.

Regarding the firm's documentation of failure investigations (Observation 2C), again Mr. Pilot stated that the failure investigations were not required to be documented.

However, all activities required under Corrective and Preventive Action, in 21 C.F.R. Part 820, shall be documented. Part of the firm's evaluation of CAPA was to determine if any other devices manufactured by the firm could show similar signs of failure due to similar methods of manufacture. Mr. Cornwell admitted that an analysis was done and a determination was made, yet there is no documentation to support his claim.

FD-483 ITEM 3.1 - On X ' CPAR . . was initiated in response to complaint X X received on X which found that ' X IUP units returned for evaluation failed the — Test. Review of CPAR X ound that the complaint failure investigation did not consider the following points in root cause analysis,

A. A review of the preventative maintenance performed on the mold prior to the affected lots being manufactured;

X X X X X X X X

C. A review of the Device History Records (DHR) for the affected lots (111757 & 111758), which require — inspection for — function prior to release of the finished product;
D. A review of the mold qualification;
E. A review of the machine set up/operation parameters.

DISCUSSION OF ITEMS 3.1 A-E - On X ' CPAR #X was initiated in a response to complaint ' ' X ' (Exhibits 33 & 34). The complainant reported IUP catheters that would not zero properly after insertion (intrauterine) (Exhibit 33).

The complainant returned devices to UTMD for analysis. After testing, UTMD engineer determined that devices failed.

The was noted in the failure investigation, when known.

The CPAR states that,

The CPAR states the following,

From the CPAR it is noted that manufacturing was experiencing defects in the Further, the engineer found that the Yet, the Preventative Maintenance of the were not examined to determine if the maintenance schedule was adequate, as part of a preventive measure for future

Observation 3.1B was removed from the FDA-483. Mr. J. Smith provided a Molding Set-Up Sheet, Master for the molding of the during the inspection (Exhibit 35). I understood that Mr. J. Smith was telling me that the Master sheet was the sheet that documented the "actual" running parameters of the molding equipment for a particular lot of product.

However, Mr. J. Smith stated during the 483 discussion that the Master document tells the machine operator how the molding equipment should be set-up to manufacture a particular part.

Due to the misunderstanding the item was scratched.

The firm inspects finished devices, IUP catheters for functionality prior to distribution. However, devices returned still failed. There is no indication that firm personnel reviewed the DHR (Work Order) for the returned lots, , to determine why or how the devices passed a inspection yet returned from the field non-functional.

My review of DHRs [redacted] revealed that the [redacted] Test had not been signed off as having been performed and the tracking form is not maintained as part of the DHR (Exhibits 37 & 38).

During the inspection and a review of this complaint, I asked Mr. J. Smith if the mold was qualified. Mr. J. Smith stated that he did not know because the part had been in use for a long time. No molding qualification was provided for my review.

In subsequent conversation with Mr. Cornwell, during the inspection, he stated that the mold is qualified [redacted] they used it because they do in process sampling of the molded parts.

However, the Molding Run Sheet (Exhibit 36.1) indicates that the mold was "new".

There is no evidence that firm personnel performed the qualification of the new mold to determine if the mold was suitable for use going into the molding production run.

Finally, the Master record is supposed to be used as a template for the set-up and operational parameters of the molding run (Exhibit 35). There is no indication that firm personnel reviewed the DHR (Work Order) for the molded part to determine if the machine was operating within established limits at the time of production (Exhibit 36).

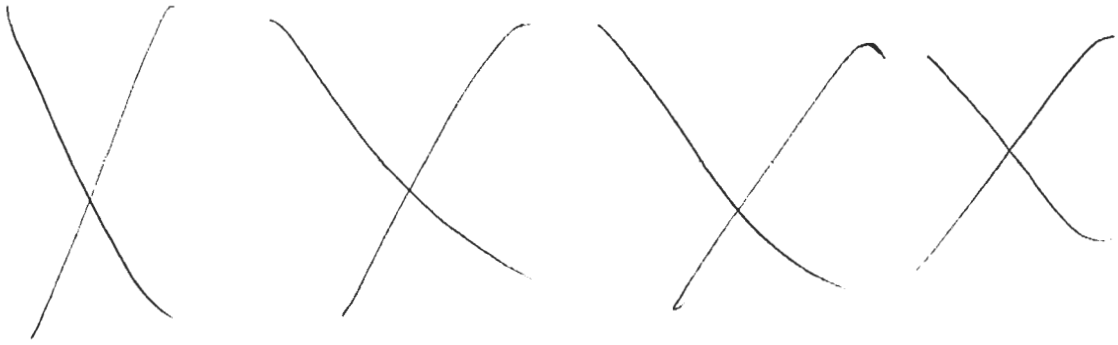
The DHR (Work Order) for the molded [redacted], [redacted] ontains a Molding Run Sheet. The Molding Run Sheet does not document the "actual" parameters at which the machine was operated to mold the part (Exhibit 36).

The only parameter that is indicated on the Molding Run Sheet is the Mold Heater Temp. The Mold Heater Temp. is not a parameter, which is listed on the molding Master document (Exhibit 35).

The Master Molding Set-Up Sheet requires the machinery to be operated within certain specifications. [redacted]

There is no indication on the Molding Run Sheet that these parameters were maintained during production of the parts.

Additionally, the Clamp force is to be set at [redacted] where the [redacted] indicates, [redacted]. Again, there is no notation on the Molding Run Sheet that indicates what the Clamp force was during production.



[Tape 2, Side 1] Exhibit 70

At the onset of discussions for this item, Mr. Cornwell wanted to explain the purpose and function of the [redacted]. He stated that the firm had [redacted] the problem with the [redacted].

Mr. Cornwell had explained to me, in great detail the function and purpose of the [redacted] during the inspection. At that time, Mr. Cornwell stated that the part was insignificant because it was only there to make the nurses feel better. He explained that the nurses needed a nice base line by which to judge the strength of the contractions, and by having the zero switch, the nice baseline was established. He stated that the nurses didn't understand the negative readings they would get if the baseline was not established.

Mr. Cornwell went on to say that the firm manufactures the same device without the [redacted] which is proof that the [redacted] is not necessary for the functioning of the device.

I explained to Mr. Cornwell that it was not the point that the [redacted] was insignificant in his mind or that there was no patient harm associated with the [redacted] failure. The point was that a device is designed to serve a user need and that the device is expected to function properly before and after it enters distribution.

During the close out discussion, Mr. Cornwell wanted to reiterate his point regarding the purpose of the [redacted] I reminded Mr. Cornwell that we had the discussion previously but if he wanted to present his point again, such that it could be recorded for the official record, that would be fine.

[redacted] Mr. Cornwell stated, "That doesn't threaten me at all." Meaning my offer to let him make his statement for the official record. Then Mr. Cornwell stated, "If you want to try to intimidate me

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you can, but I am not intimidated." "Your implication of what you just said was an attempt to intimidate me. And, I am not intimidated." (Exhibit 70, Tape 2, Side 1).

Mr. E. Smith stated that he did not interpret my comments as an attempt to intimidate Mr. Cornwell.
Mr. Cornwell went on to describe the function of the — He stated that if the — does not ——————————————— does not short out and the device does not zero.

The function of the — is to be held in place while the monitor is zeroed. If the — moves out of place then the zero is not accurate and negative pressure readings may occur.

Mr. Cornwell stated that it is routine after millions of uses of the device, that nurses "know" to hold the — in place while the monitor is zeroed (Exhibit 70, Tape 2, Side 1).

Mr. Cornwell stated that the damaging part of the complaint, [redacted] was that the engineer characterized [redacted] % of the units as failing (Exhibit 33).

Mr. Cornwell stated that the failure event was an aberration since no other complaints had been received.

Mr. Cornwell stated that they consider the inability of the to maintain its position on the catheter " [redacted] ." (Exhibit 70, Tape 2, Side 1) However, the weakness was characterized as not being significant because all the nurse does is hold the — in place and the zero is achieved.

Mr. Cornwell stated that, "It is not a molding problem." The way they check the part is a functional test. They install them and check that they are working.

NOTE: The [redacted] functional test on the lots containing the failed units did not detect the failing units before they were distributed.

Mr. Cornwell said that they (UTMD) internally [redacted] the situation. It is not a significant problem. He did not see it as a failure of the Quality System.

Mr. Cornwell stated that in the trouble-shooting manual, they tell the user facility that if they zero the catheter correctly before inserting it into the uterus, then subsequent zeroing shouldn't be necessary. They do not instruct the nurse to hold the switch in place when re-zeroing after insertion. According to Mr. Cornwell, the problem only occurs after the product is inside the uterus.

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NOTE: Instructions for use include instructions for zeroing the catheter post insertion (Exhibit 69A.6-69A.13).

After Mr. Cornwell's assertions, I explained that the Observation did not relate to the relevancy of the [redacted]. The Observation relates to the follow up of the complaint and the CPAR in determining what caused the failure.

I informed Mr. Cornwell that UTMD's own failure investigation found that the failure was due to a [redacted]
Regarding qualification of the mold, Mr. Cornwell stated that the qualification was clear. If the part doesn't work, they throw it away. The qualification is that the part works or it doesn't work.

When I told Mr. Cornwell that [redacted] of the parts returned failed, he stated that it was a [redacted] That Quality Engineering made the parts fail.

Mr. Cornwell continued to state that the failure was not a [redacted] problem. He stated that they had [redacted] He didn't know why the Engineer reported that the mold needed to be resurfaced.

Mr. Shirley stated that, "It was a new engineer." (Exhibit 70, Tape 2, Side 1).

Mr. Cornwell stated that they are always trying to [redacted]

A discussion ensued over the Master Molding Set-Up Sheet (Exhibit 35). The discussion revealed that I thought Mr. J. Smith told me, during the inspection, the Master sheet was how the Work Order [redacted] for the molded [redacted] was run. Mr. J. Smith stated, during the 483 discussion that the Master is the standard operating parameters for the molding equipment.

Observations 3.1B and 3.2 (because it dealt with the molding sheet as well) were stricken from the FDA-483 on my decision.

Regardless of the issue over the Master Molding Set-Up Sheet, Mr. Shirley continued to state that there is no set standard for a molded part on the Clamp pressure/force parameter. [redacted]

Mr. Pilot stated that I was looking for a tolerance limit for Clamp pressure. Mr. Pilot stated that, that was not a routinely accepted practice in the industry.

However, discussion with FDA's National Expert in Medical Devices, Mr. Norman Wong on 4/23/02 indicated that, Clamp pressure is a function of Injection

pressure. The purpose of process validation (molding process validation) is to optimize the lowest clamp pressure to the highest injection pressure to produce the desired results. A working specification range for both Clamp pressure and Injection pressure should have been established.

A review of the Master Molding Set-Up Sheet shows that there is no range of operation for the Clamp pressure (Exhibit 35).

Mr. Cornwell continued to describe the molding issue with this [redacted] as an insignificant quality issue. I continued to explain to Mr. Cornwell that I was addressing the adequacy of the failure investigation, complaint follow up, and corrective and preventive action systems, to determine the root cause for failures so that a subsequent failure could be prevented in the future.

NOTE: Failed components were manufactured from [redacted] different cavities in the mold. Failures coming from the same cavity of the mold may indicate a mold issue. However, failures coming from multiple cavities of the mold may indicate operating parameter issues such as time, temperature, clamp pressure, injection pressure. The source of this information was through discussion with FDA's National Expert in Medical Devices, Mr. Norm Wong on 4/24/02.

Finally, UTMD Engineer [redacted] states in his failure analysis, '[redacted]

Again, as Mr. Wong explained to me, part shrinkage is not associated with clamp force or injection pressure. Park shrinkage is associated with mold temperature and rate of cooling.

The mold temperature is indicated on the Molding Run Sheet as either [redacted] degrees (Celsius or Fahrenheit is unknown) (Exhibit 36.1). However, the Master Molding Set-Up Sheet does not denote the mold temperature at which the component should be molded (Exhibit 35).

(The Master Molding Set-Up Sheet states that it is [redacted] I never observed the [redacted] of this document and the [redacted] was not provided to me.)

At the end of the discussion with management on this Observation, Mr. Pilot again returned to the theme that the firm does not have to document all decisions made. However, the decisions made in a complaint failure investigation are required to be maintained as part of the complaint file.

Mr. Cornwell continued to state that the issue with the [redacted] was a [redacted] issue not a [redacted] issue, and that the [redacted] issue was continuing to be addressed and had been addressed over the past [redacted]

I explained that the CPAR should not have described the failure as a [redacted] issue if it was not one. Mr. J. Smith was the final signature on the CPAR closing dated [redacted] (Exhibit 34). None of the [redacted] individuals signing the CPAR disagreed with the findings of the Engineer.

The only corrective action taken or reviewed by the engineer, as is evidenced by the CPAR, was a to r [redacted]. None of the other issues stated above have been addressed by UTMD.

[redacted]

DISCUSSION OF ITEM 3.2 – This observation was scratched due to a miscommunication with firm's management. See Discussion of Items 3.1A-E above.

FD-483 ITEM 4.1 - A review of the firm's Device History Records (DHR) for the Intran Plus product line revealed that [redacted] DHRs reviewed did not identify and/or document the disposition of all devices within the lot. For example,

A. Lot 120127 had [redacted] devices accepted at the [redacted] Test", prior to the "Final Test". Only [redacted] devices entered the Final Test; there is no record of the [redacted] device discrepancy. Further, from the Final Test [redacted] devices were accepted. However, only [redacted] devices were released to sterilization. There is no documentation of the [redacted] device discrepancy;
B. Lot 120047 had [redacted] devices accepted at the [redacted] Test. However, [redacted] devices entered the next test station Final Test. There is no explanation as to where the [redacted] devices entering the Final Test came from. Additionally, the Final Test approved [redacted] devices; however, only [redacted] devices entered sterilization. There is no explanation for the [redacted] device discrepancy.

DISCUSSION OF ITEMS 4.1A-B – [redacted] DHRs (Work Orders) were selected for review. The sample was made according to the [redacted] The purpose of the examination was to determine if the firm was documenting the disposition of the devices under the Work Order.

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[illegible] DHRs reviewed had some discrepancy. Specifically, either devices were missing and unaccounted for from one inspectional/operational step to the next, or additional devices had been added to the lot between inspectional/operational steps.

Specifically, lot120127 of [illegible], called for the manufacture of [illegible] IUP-400 devices (Exhibit 40). At the [illegible] Test [illegible] devices were accepted, [illegible] devices were rejected for a total of [illegible] devices. However, the Final Test was only performed on [illegible] devices. The final test is a [illegible] inspection of all devices. There was no indication in the DHR where the [illegible] devices from the [illegible] Test to the Final Test went.

Between the steps of [illegible]. The DHR does not indicate that any devices were rejected at this operation.

At the Final Test, [illegible] devices were accepted. At pre-sterilization only [illegible] devices went for sterilization. There is no indication where the [illegible] devices went between the Final Test and sterilization.

Between the Final Test and pre-sterilization there are several steps, including, [illegible] is it indicated in the DHR that devices were rejected.

Likewise, lot 120047 of [illegible], called for the manufacture of [illegible] IUP-400 devices (Exhibit 41). At the [illegible] Test [illegible] devices were accepted, [illegible] devices were rejected. At the Final Test, [illegible] devices were tested. There is no record of where the [illegible] devices entering the Final Test came from. The [illegible] Test allows for [illegible] Any products that cannot be reworked satisfactorily are rejected. The number indicated on the DHR as rejected at the [illegible] Test are those devices that could not be reworked.

There is no point beyond the [illegible] Test where rejected catheters should have been reintroduced into production.

The Final Test approved [illegible] devices. However, only [illegible] entered pre-sterilization. There is no accounting for where the [illegible] devices went from the Final Test to pre-sterilization.

Again, there are several steps between Final Test and pre-sterilization, but no where in the DHR is there documentation that devices were rejected at any of the intermediary steps.

Additional examples can be seen on DHRs [redacted]. (Exhibits 43-44 & 46).

Mr. Cornwell had no comment on the Observation because firm personnel needed to review the referenced DHRs.

[Tape 2, Side 2] Exhibit 70

FD-483 ITEM 4.2 - DHRs do not accurately reflect the in-process testing being performed, in that

A. The individual signing the test results on the Bill Of Operations (BOO) is not the individual actually performing the in-process test/inspection. Specifically, Form [redacted] for DHR [redacted] indicates that the [redacted] Test was performed by operators ' [redacted] " and [redacted] '; however the DHR test results were signed by ' [redacted] ";
B. The procedure [redacted] Work Order Operation Tracking Form does not require the inspection results to be reviewed and the number of units inspected to be tallied by the individual signing the DHR thus, affirming that the inspections/tests were actually conducted.

DISCUSSION OF ITEMS 4.2 A-B - The DHR (Work Order) for Lot 120471 was reviewed (Exhibit 46). Specifically, I asked Mr. J. Smith to retrieve for me, [redacted] Work Order Tracking Forms : [redacted] for W.O. [redacted] from the production room floor (Exhibit 45). [redacted]

I reviewed the forms [redacted] for W.O. [redacted] against the W.O. in-process testing release. The W.O. indicates that an individual named [redacted] signed the W.O. as having completed operations, [redacted] (Exhibits 46.7-46.8).

However, Forms [redacted] indicate that the [redacted] operation was performed on [redacted] Further, the [redacted] Test was performed by [redacted]

The individuals actually performing the work are not the individuals signing the W.O. Further, because the forms [redacted] are thrown away, the record of the individual actually performing the testing steps is lost and not part of the DHR.

The UTMD procedure for using form [redacted] is titled, "Work Order Operation Tracking Form" (Exhibit 47). The procedure indicates that the [redacted]

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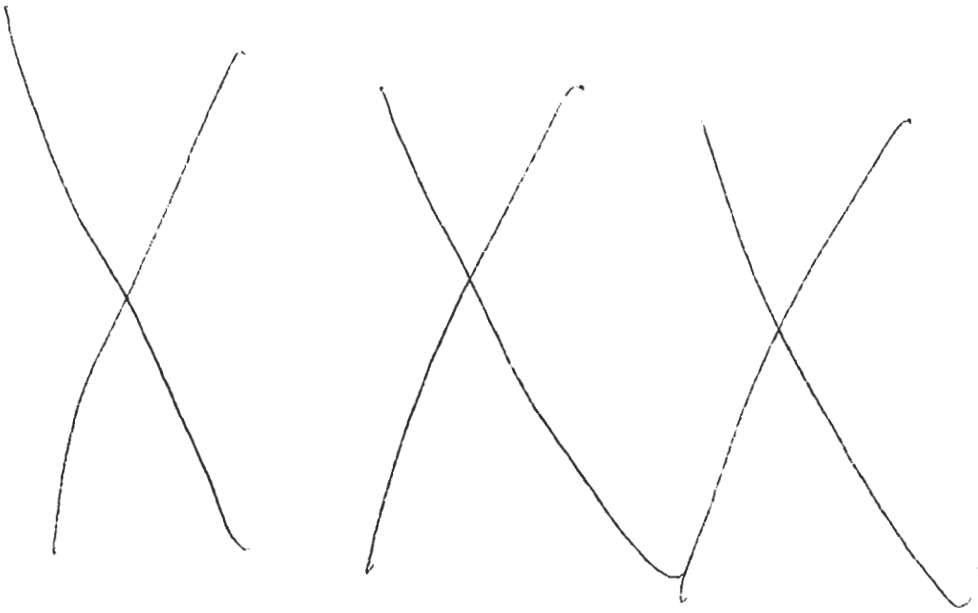

Procedures for the [redacted] procedure instruct the operator to indicate the inspection procedure was done by completing form X

Mr. Cornwell stated his position that form X is not an acceptance tool, it is a monitoring tool to see where the operators are in the process. The acceptance testing performed by the firm is the X functional testing of the device at the end of the procedure.

FD-483 ITEMS 4.3 - DHRs do not reflect retest/rework activities, which are allowed to be performed without the issuance of a Non-Conforming Materials Report (NCMR). Specifically,

A. Procedures X X X X X X X X X X X X X X X X X X X X X X X X X allow for retest and rework activities without those activities being documented in the DHR;
B. Further, there is no justification for the acceptance of retest "pass" results for devices, which failed the first test and passed the second test, without rework activities being performed to correct the initial failure.

DISCUSSION OF ITEMS 4.3 A-B

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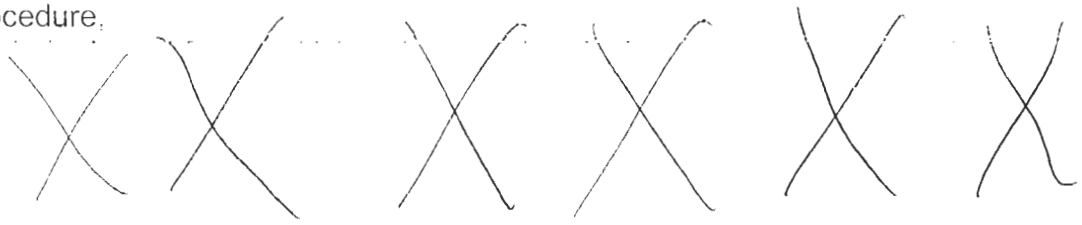
Procedure, [illegible] states that rejected products may be retested (Exhibit 48). Products that pass the retest are accepted. The retest activities are not documented.

Mr. Shirley stated that if the device fails the first test and passes the second, it was an operator error or machine error, which originally failed the part.

There is no procedure for determining if the operator is incorrectly performing the test and devices are failing or for examining the functioning of the tester to determine why it would give a failing result the first time and not the second.

Procedure, [illegible] allows units failing the [illegible] to be reworked, first by replacing the [illegible] If the unit still fails, then the unit can be reworked again by replacing the [illegible] The rework activities are not documented in the DHR/Work Order.

Procedure,



The [illegible] seem to contradict each other, first stating [illegible], must be scrapped, then stating [illegible], may be retested.

The procedure allows the units to be retested without any rework on the unit to correct the initial failure, or a determination of the what the initial failure was. The procedure calls for the production of the [illegible] however the report does not state how many units initially failed then passed on retest. [illegible]

Mr. Pilot asked if the firm's procedures require them to document rework and retest activities. I told him that the procedures do not require the documentation but that the documentation should be required by procedure. Mr. Pilot stated that it was only my opinion that these steps should be documented.

However, acceptance activities are required to be documented. Testing and retesting of a device is an acceptance activity. Additionally, rework activities are required to be documented in the DHR.

FD-483 ITEM 5 - Not all significant quality data are being captured and reviewed in that,

A. Form X does not reflect at which inspection step devices were rejected or accepted and does not indicate the number of units accepted or rejected;
B. Form X is discarded thus, information, which may be useful in a failure investigation is lost (i.e. who the inspector was).

DISCUSSION OF ITEM 5

Form X (Exhibit 45) is being used as an acceptance tool as described in Observation 4.2 A-B.

Specifically, by procedure, operators are required to complete form X to document that in-process testing, X X X X X X X X X X X X X X are being completed. Further, the DHR/Work Order instructs the operator at the X , X X X , to record their activities on form X . However, by procedure (Exhibit 47) for completing form X the form is discarded and not maintained as part of the DHR/Work Order.

The DHR is signed by someone other than the operator actually performing the inspectional step. The individual signing the DHR/Work Order does not have a requirement by procedure to verify the number of devices examined that he/she records on the DHR.

Further, form X is a record of in process inspectional activities but does not reflect the number of devices rejected or accepted at each step. It is unknown how the individual signing the DHR and recording the total number of accepted and rejected devices at each test, arrives at those values.

Additionally, form X records the initials of the operator performing the inspectional step. Form X, by procedure, is discarded. Thus, the name of the individual conducting the acceptance activity is lost. That information may be useful in a device failure investigation, regarding issues of training or in determining who handled the device when it was manufactured.

Per Regulation, the activity, date, result, operator signature and equipment used for the acceptance activity are to be recorded in the DHR.

Firm personnel had no comments on this observation.

FD-483 ITEM 6 - Review of the firm's Preventative Maintenance program for equipment used in device manufacturing revealed that,

A. Procedure X XX, Preventative and Unscheduled Maintenance states that unscheduled maintenance will be tracked and trended at least on an

[redacted] Although data of unscheduled maintenance are being tracked, there is no evidence that trending analysis is being performed. Further, the last Preventive Maintenance Annual review minutes dated [redacted] do not mention a review or analysis of unscheduled maintenance;

B. From [redacted] there were [redacted] instances of the [redacted] going off on the [redacted] machine, responsible for manufacturing [redacted] devices. A Corrective Action was not generated for these reoccurring alarms, there was no evaluation of the machine's performance in view of the alarms, there was no evaluation of the effect the cause of the alarm may have on the production of devices and no cause for the alarms was ever determined.

DISCUSSION OF ITEM 6

The "Preventative Maintenance and Unscheduled Maintenance Procedure" is divided into two distinct sections, "Preventative Maintenance Procedure" and the "Unscheduled Maintenance Procedure" (Exhibit 52).

The procedure states that unscheduled maintenance will be tracked and trended at least on [redacted] There was no evidence of trending being performed for unscheduled maintenance activities.

I asked Mr. J. Smith if there was any trending performed for the unscheduled maintenance activities. Mr. J. Smith stated that they could look at the tracking report and see that there were no trends.

No trending information was presented for my review.

A review of the Preventive Maintenance Annual Review Minutes (Exhibit 53) found no mention of trending being performed for either Preventative Maintenance or Unscheduled Preventative Maintenance.

There was no mention of unscheduled maintenance at all, including the number of activities, the types of activities, problems or areas that needed to be addressed. [redacted]

A review of the unscheduled maintenance report found that there were [redacted] occurrences of alarms going off on the [redacted] used to manufacture [redacted] devices (Exhibit 54).

Mr. J. Smith stated that the [redacted] machine is used to perform almost the entire assembly process for the [redacted] line of devices.

Alarms began going off in [redacted] alarms occurred between [redacted] The repair for the alarm on [redacted] stated that it was an unknown fix and the problem was intermittent.

The alarms continued and on [redacted] the repair statement was that the issue was still not fixed but the machine was running.

Alarms continued going off, and on [redacted] the repair statement was that work was being done on trouble shooting the [redacted] The problem was still not fixed but the machine was running. The reason for the alarms was unknown.

Again, as described by Mr. J. Smith, this assembly machine is responsible for almost all aspects of the [redacted] device assembly.

There were [redacted] alarms in [redacted]. No trending was reported.
There was no official corrective action initiated (CPAR). The firm could not produce evidence that anyone considered what effect the alarms may have on the production of the device.

Mr. Cornwell stated that just because an alarm goes off doesn't mean there is anything wrong with the equipment. He stated that the machine is [redacted] and that alarms are built in to the [redacted] to prevent problems with the device.

The cause of these alarms was never determined and a final corrective action was never noted on the unscheduled maintenance report.

FD-483 ITEM 7 - There is no documented statistical rationale for the sampling plans used in component manufacturing in-process inspection, or Intran Plus Catheter Final Inspection. Specifically,

A. Lot 111409 consisted of the manufacture of [redacted] component parts [redacted], of that [redacted] devices were selected for sampling with no statistical rationale;
B. IUP lots are broken down into batches of [redacted] for sampling purposes. The number of units sampled is always [redacted] There is no statistical justification for sampling [redacted]" devices. (Lots 111757, 111758)
C. [redacted]. However, the process qualification failed to explain the statistical rational behind the selection of [redacted] test units used for the [redacted]

DISCUSSION OF ITEMS 7A-C

Lot 111409 was for the manufacture of part [redacted]
The lot consisted of [redacted] components [redacted], being manufactured, of that [redacted] components were sampled. [redacted]

Mr. J. Smith admitted during the close out discussions that the [redacted] are sampled, if they are okay, then the process continues, if they are not okay, then adjustments are made. Mr. Cornwell made the statement and Mr. J. Smith agreed, that the sampling is used to monitor the process [redacted]

As the sampling is used to control and monitor a process [redacted], it is necessary that the sampling conducted is representative of the lot. There is no statistical rationale to describe [redacted] units sampled as being representative of the lot.

Mr. J. Smith stated during the inspection, that the number of samples taken is dependent on how many parts the firm is willing to throw away. Mr. Cornwell supported this statement in the closing discussions.

Mr. Pilot stated that the firm could elect to discontinue any sampling and there would be no problem (Exhibit 70, Tape 2, Side 2).

However, elimination of sampling during a [redacted] process would eliminate the control of the [redacted] process that is currently being provided by the sampling activities.

The Catheter Final Inspection is the last inspection of the device before it goes into packaging (Exhibit 51). The inspection includes looking for missing or incorrect parts or components, inspecting the tip of the catheter for voids and looking for cosmetic defects.

Per the procedure, [redacted] devices are to be sampled from each tote. Each tote is to consist of [redacted] devices or less.

There is no reference to the sampling plan, standard or rationale used for this sampling scheme. Examples of the sampling can be seen in DHRs [redacted]

Again Mr. Cornwell and Mr. J. Smith stated that the sampling did not have to be based on any statistical rationale.

However, statistical techniques should be used when verifying the acceptability of a process capability and product characteristics. Product characteristics are examined in this sampling step. The inspection is looking to make sure components and parts of the finished device have not been left off the device and that the tip of the catheter has been formed properly and has left no voids.

[Tape 3, Side 1] Exhibit 70

In [redacted] UTMD changed the [redacted] devices. The design change eliminated the [redacted]

The "[redacted]" not only qualified the [redacted] This is seen in the functional testing done to confirm the [redacted] could be manufactured and applied such that the device would function as intended.

There were [redacted] tests done in the qualification. [redacted]. The number of units sampled were [redacted] respectively.

Again, the testing was done as a process qualification. There is no documentation to support any statistical rationale for the selection of these sample sizes.

I spoke to [redacted] who prepared the qualification. I asked [redacted] why the numbers were chosen for the samples. [redacted] stated that they manufactured [redacted] devices with the [redacted] for the qualification. [redacted] She stated that there was no statistical rationale for the total number of devices manufactured for the qualification, [redacted] or for the sample sizes chosen.

Mr. Cornwell stated that the [redacted] He stated that a full qualification of that design and process was done based on the fact that [redacted] of units had been distributed and there had been few instances of complaints.

Mr. Cornwell stated that the qualification was based on historical experience of using the same process with just a slightly different [redacted]

I told Mr. Cornwell that FDA does not normally recognize historical validation only because there is seldom all of the documentation necessary to support the claims. However, if that was the route the firm was going to follow, then there should have been some analysis of the historical data to support retrospective validation.

Mr. Cornwell stated that the firm had the historical data and had reviewed it before making the decision to do a [redacted] sampling in the qualification. He suggested that I should have reviewed the history of complaints, reworks,

NCMRs and other quality data to support the firm's use of retrospective validation.

I replied that it was the firm's responsibility to review the data and state what they reviewed and what the conclusions were to support a historical validation and reduced sampling plan in the qualification.

Mr. Pilot stated that the firm needed to pull together the documentation reviewed and used to support their use of a [redacted] sampling plan in the process qualification.

FD-483 ITEM 8 - Procedure [redacted] Change Proposals does not ensure that document changes are evaluated to determine the other areas of the quality
RACO 4/15/02
system that may be affected by the change. For example, on [redacted] for IUP devices was corrected to reflect a change in [redacted] However, device failure test specifications in complaints [redacted] were not changed and remained at [redacted]

DISCUSSION OF ITEM 8

The procedure for "Change Proposals", [redacted] does not have a requirement to ensure that approved changes are communicated to appropriate personnel in a timely manner.

Specifically, the Device Master Record (DMR) (Exhibit 57), for Intran Sensor Tipped Catheters had the [redacted] changed from [redacted] on Change Proposal [redacted]

However, test reports, generated in response to complaints of catheter failures, indicate that the change in the specification in the DMR was not communicated to the testing engineers.

[redacted] DHRs/Work Orders were selected for review. The sample was made according to the [redacted] records reviewed did not have the appropriate changes made in the test specifications.

Specifically, the specification as seen in complaints [redacted] on the complaint evaluation form, still had the specification listed as [redacted] (Exhibits 59.6 & 60.7). These complaints were reviewed by engineering [redacted] after the Change to the DMR was approved.

I explained to Mr. Cornwell that the issue was not that the tolerances used in testing the devices were ✕ but that the change in the specifications was not communicated to the engineers who rely on the information for proper failure investigation.

Had the specifications been made ✕ in the Change, then the results of the failure investigation may have been different.

Mr. Shirley stated that the complaint evaluation sheet, used by the engineers in complaint failure investigations, is not a controlled document and therefore, does not need to be changed.

I disagreed in that, if a change is made to a device or device specification, then the engineers who conduct failure investigations need to know about those changes. Regardless of whether or not the complaint evaluation sheet is controlled, the engineer still needs to have the correct information regarding the device in order to conduct an accurate failure investigation.

In this instance, the engineer conducting a failure investigation is the appropriate personnel that needs to be notified in a timely manner of the change.

If the specification listed on the complaint evaluation sheet was obtained by the investigating engineer, then either 1) the changed DMR did not reach the engineer prior to his tests being performed; or, 2) the engineer received the change and did not either read it, or implement it when recording the specification on the complaint evaluation form.

Again, the Observation does not relate to the ✕ of the specification but the communication in change control.

Mr. Pilot stated that because the complaint evaluation form, which contains the specification is not a controlled document, then the document control requirements do not apply.

However, the controlled document in question is the DMR. The DMR was changed. The change to that controlled document is required to be communicated, in a timely manner, to appropriate personnel. Again, the engineer who relies on the information contained in the DMR for conducting failure investigations, is appropriate personnel.

FD-483 ITEM 9 - Internal Quality Audits have failed to identify and correct deviations from the Quality System Requirement in the following areas:

A. Validation;
B. Change Control;

C. Corrective and Preventive Actions;
D. Device History Records; as is documented by the observations on this FDA-483.

DISCUSSION OF ITEM 9

This Observation was based on Observations 1.1-1.4; 2; 3.1; 4.1-4.2 and 8. The intent of the quality audit is to ensure that procedures are written in accordance with the QSR and that operations performed by firm personnel not only comply with the firm's own procedures but with the Quality System Regulation.

Mr. Pilot stated that firm personnel do not agree that the Observations on the FDA-483 are deviations from the QSR and therefore, would not have been expected to have discovered and corrected any of these issues through the internal quality audit.

I stated that I believed the Observations to be deviations from the QSR and thus should have been detected by the internal quality audit system.

Mr. Pilot stated that a blanket statement regarding internal quality audits was not a fair statement, particularly since the firm disagreed with my Observations.

I told Mr. Cornwell that I felt that the firm did not believe any of my Observations reflected failures by the firm. That statement was based on the nearly exclusive disagreement with firm personnel on all the Observations leading up to this one (Observations 1-8).

Mr. Cornwell stated that I was trying to intimidate him again. I told the firm personnel that they had argued nearly every Observation and that there was little agreement.

Mr. Pilot took exception to my use of the term "argue". The word "argue" can mean, to make a case for. That was the intent of my use of the word "argue". The firm's personnel had tried to make a case against nearly all of the Objectionable Conditions leading up to and including Observation 9.

The firm's personnel felt that because we disagree on the Observations then Observation 9 was not valid.

Mr. Pilot wanted to know if I was suggesting that the firm is "out of control" (Exhibit 70, Tape 3, Side 1).

Mr. Pilot went on to say that the Inspector is claiming that the system is "out of control". Mr. E. Smith reminded Mr. Pilot that the Investigator did not use the term "out of control", that term was used by Mr. Pilot.

Mr. Pilot stated that the firm's market share is an indication that the firm is in control.

Mr. E. Smith stated to Mr. Pilot that FDA's standard is the Quality System Regulation and that while the firm may use market share as a marker for them, it is not FDA's standard.

FD-483 ITEM 10 - In reviewing procedure [redacted], Corrective/Preventive Action, it was noted that,
(RACO 4/15/02)
A. The procedure does not require the following data sources to reviewed and/or analyzed

A. [redacted], preventative maintenance, both scheduled and unscheduled
B. Results of Internal Quality Audits

DISCUSSION OF ITEMS 10A-B

The procedure, for "Corrective/Preventive Action" does not require the analysis of preventative maintenance (scheduled and unscheduled) or the results of internal quality audits (Exhibit 61) as sources of quality data.

Mr. Pilot stated that the Observation was beyond the scope of the Regulation.

However, the Regulation states that internal audits and other sources of quality data shall be included in the analysis of the Corrective and Preventive Action system.

Regarding the unscheduled preventative maintenance, Observation 6 is an example of an area of the PM system that may need to be addressed by the Corrective and Preventive Action system.

The "Internal Audit Procedure" states that, [redacted] (Exhibit 62.4).
The procedure does not define which Internal Audit findings will not be sent into the CPA system. Further, the procedure does not define the term, "typically".
Mr. Pilot continued to state that the Observations should not be noted on the FDA-483.

Mr. Pilot brought up the point that the firm still had not received the EIR from the previous inspection and that the firm would be concerned about what would be reflected in this EIR.

Mr. E. Smith reminded Mr. Pilot that FDA does not have to release the previous EIR as long as there is an open case.

[Tape 3, Side 2] Exhibit 70

FD-483 ITEM 11 - Procedure [illegible], Nonconforming Materials, does not require the findings of NCMR investigations to be communicated to persons directly involved in the event which to the issuance of the NCMR.

DISCUSSION OF ITEM 11

The Observation should read, "...directly involved in the event which led to the issuance of the NCMR."

The procedure does not require that the findings of an NCMR investigation be communicated to the persons or organization responsible for the nonconformance (Exhibit 63).

Mr. J. Smith stated that the Supervisor from the area of non-conformance signs off on the NCMR investigation. However, the procedure does not state that the Supervisor responsible for the area in which the non-conformance occurred is required to sign off on the NCMR investigation. The procedure states, that members of [illegible] etc... will sign off on the disposition of the materials; it does not state the Supervisor responsible for the area of concern will sign off.

Not all NCMRs result in official Corrective and Preventive Actions being taken therefore, there is no assurance the investigation of the NCMR is communicated through that available channel. For example, NCMRs [illegible] were reviewed. [illegible] investigation of the NCMR determined that no corrective and preventive action was required.

There is no requirement for a department Supervisor to inform employees responsible for non-conformances.

If the non-conformance is with an incoming raw material, the UTMD NCMR procedure does not require that the vendor be notified of the non-conformance or that a determination be made rather or not the vendor needs to be notified (Exhibit 63).

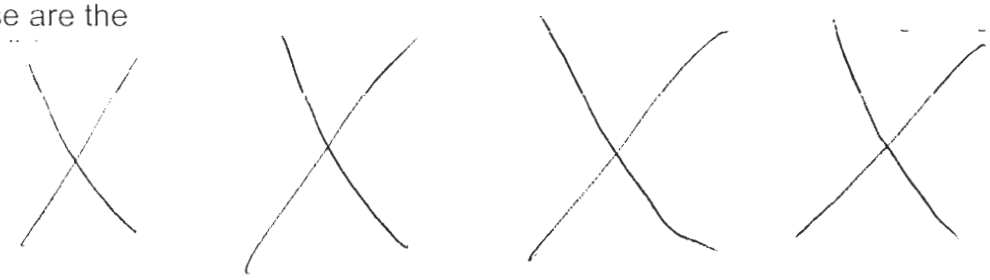
On [illegible] a raw material, product number [illegible] was received from the vendor without a Certification (Exhibit 64). The disposition of the NCMR was [illegible] Again on [illegible] the same raw material was received from the vendor with the wrong Certification. The disposition of the NCMR was again, " [illegible]

According to procedure, representatives of [redacted] will approve a disposition of [redacted] the product was not returned to the vendor therefore, the vendor might not know that a problem exists.

FD-483 ITEM 12 - The Internal Audit procedure [redacted] and the Internal Audit training program [redacted], lack a definition of specific items, which at a minimum, should be reviewed during an internal audit of each audit area, to ensure the audit is thorough and effective.

DISCUSSION OF ITEM 12

[redacted] procedures are used by UTMD to conduct Internal Quality Audits (IQA); those are the



The Internal Audit Procedure states that, '[redacted] (Exhibit 62.2) The procedure does not say anything about the QSR being audited at least once a year.

I asked Mr. J. Smith during the inspection, what areas are audited during an IQA. Mr. J. Smith provided me with an audit list (Exhibit 66).

I then asked Mr. J. Smith if there was any documentation that instructed the auditor of what to look for or what specific areas under each audit section should be reviewed.

For example, was there any documentation that instructed the auditor of Corrective and Preventive Actions on what "specifically" to look for when auditing those records?

Mr. J. Smith stated that the instructions for conducting audits are outlined in the procedures (Exhibits 62 & 65). However, the procedures do not specifically instruct the auditors on the critical areas of each audit section that should be reviewed.

The Audit Plan, Form [illegible] outlines what the auditor has chosen to review during their audit but does not describe what aspects of each area need to be or must be reviewed during each audit.

Further post-inspectional review of the audit schedule revealed that the schedule **does not** contain a provision for auditing the firm's complaint system (Exhibit 66). The Corrective and Preventive Action system is included but not all complaints result in CPARs being issued.

Mr. Pilot stated that the Regulation does not require that the procedures define what specific areas of the quality system should be audited. Mr. Pilot asked that the item be removed from the 483.

FD-483 ITEM 13 - Software systems are being used as an integral part of the Quality System. [illegible]

There are no procedures for the:

A. Validation of systems to ensure the accuracy, reliability, consistent intended performance or the ability to discern invalid or altered records;
B. The ability to generate accurate and complete records;
C. Protection of records throughout the record retention period;
D. Limit of system access;
E. Audit trails that are computer generated and time stamped to independently record the date and time of operator's entries and actions.

DISCUSSION OF ITEM 13

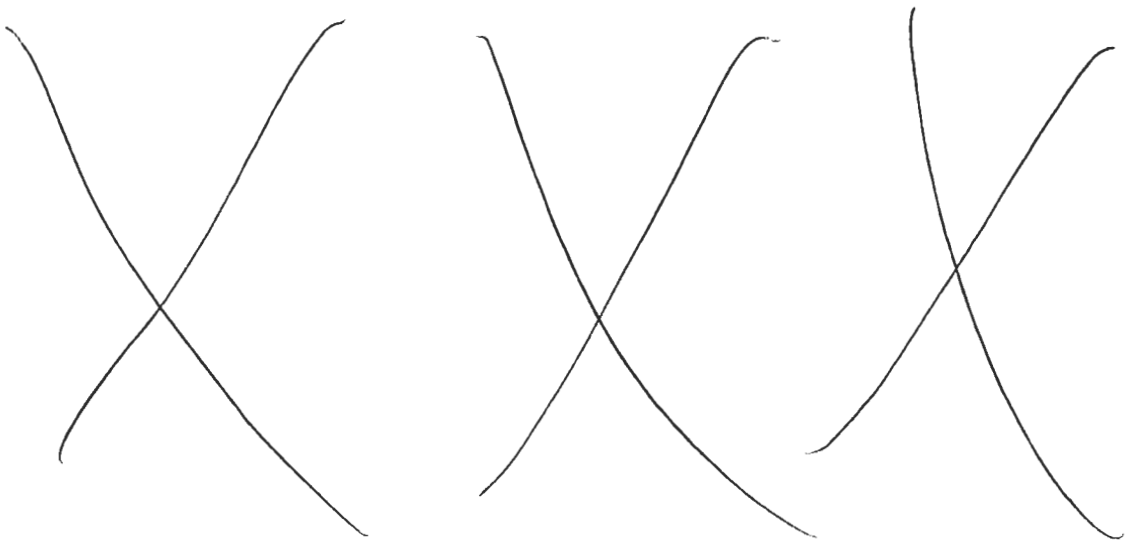
Software systems are being used by UTMD for controlling parts of the Quality System.

For example, the incoming materials inspections are conducted in accordance with procedure, "Receiving Inspection" [illegible] (Exhibit 67). The procedure states that the inspector using the ANSI/ASQC Z1.4 sampling table should [illegible]

There are no procedures for the validation or control of this software system. Documents are controlled in both electronic format and hard copy format depending on the necessity of the user, according to Procedure, "Document and Data Approval, Issue and Control", . (Exhibit 68)

The Procedure states, "Once a document or data is approved, it is released in

There are no procedures for the validation or control of this electronic system.



Again, there are no procedures for the validation or control of this electronic system.

Not noted in the Observation is the fact that unscheduled preventative maintenance activities are stored and tracked using the [redacted] (Exhibit 52.2). The storage and tracking of the quality data is maintained [redacted] There are no procedures addressing the validation of this system.

Mr. Cornwell stated that UTMD relies on [redacted]

However, a review of the procedures seems to contradict Mr. Cornwell's assertion.

This ended the discussion of the FDA-483 Observations.

Further Discussion with Firm Management

The following comments may be found on Tape 3, Side 2. (Exhibit 70)

I told Mr. Cornwell that I had an Affidavit and documentation of Interstate Commerce that I wanted to present to him.

Mr. Pilot immediately demanded that I make a copy of the Affidavit for Mr. Cornwell. Mr. Pilot did not want to see the Affidavit, he just wanted Mr. Cornwell to have a copy of the Affidavit.

I explained that it is the District policy that I do not provide a copy of the Affidavit to the firm unless the firm's representative decides to sign the Affidavit.
Mr. Pilot stated that my assertion of District policy was not true. Then instructed me to destroy the Affidavit in the firm's presence if I was not going to provide them with a copy.

Mr. Pilot then stated that I was refusing to provide a copy of the Affidavit to the firm to read. I told him that Mr. Cornwell could read the Affidavit but that I would not provide a copy of the Affidavit unless Mr. Cornwell signed it.

Mr. Pilot stated that if that was the District policy then the company was not going to review the Affidavit.

Mr. Pilot wanted to know if Mr. E. Smith wanted to contradict or make an exception to the District policy on Affidavits.

Mr. E. Smith stated that he did not intend to do either.
Mr. Cornwell stated that he had to follow Mr. Pilot's advice, and under the proposed terms, not review or sign the Affidavit.

Mr. Cornwell then read a written statement regarding his views and opinions of the firm's operations and the inspection.

In summary of Mr. Cornwell's statements:

Mr. Cornwell stated that he believed that UTMD is in compliance with all of the applicable provisions of the QSR.

Mr. Cornwell stated that I told him that since 1999 FDA has not "focused" on complaints or safety issues in compliance inspections. (See my response under Investigator's Remarks).

Mr. Cornwell began by providing statistics on the number of devices manufactured and distributed by UTMD versus the number of product liability lawsuits, complaints and MDRs.

Mr. Cornwell stated that [redacted] units shipped in [redacted] were molded components used by other companies. [redacted]

Mr. Cornwell again stated that I had suggested (during the inspection) that the molding operation was "out of control", which was not evidenced, in Mr. Cornwell's opinion, by the number of complaints received on molded parts. (See my response under Investigator's Remarks).

Mr. Cornwell stated that the Intran line of devices are used to make life and death intervention decisions in high risk births.

Mr. Cornwell referenced the three MDRs filed by the firm in the last year. Mr. Cornwell stated that each of those MDRs was as a result of improper handling of the Umbilicath by the clinician. (See my response under Investigator's Remarks).

Mr. Cornwell then read the definition of "Validation" from 21 C.F.R. Part 820. He then stated that the fact that the firm has had [redacted] was validation of the firm's quality system.

He stated that it was his responsibility to implement the QSR and at the same time remain competitive in the market place. Mr. Cornwell stated that the inspection taxed the ability of the firm to remain in business from a resource point of view. (See my response under Investigator's Remarks).

In Mr. Cornwell's "expert" opinion, UTMD is performing at a high quality standard. Mr. Cornwell stated that he is frequently involved and personally reviews the day to day operations of the firm.

Mr. Cornwell stated that the firm's quality system is adequate to meet the QSR with reasonable proportion and business context.

Mr. Cornwell again stated, that I stated, that UTMD's business costs may be spiraling "out of control" as a result of lack of control in manufacturing. (See my response under Investigator's Remarks).

Mr. Cornwell recommended that I review the firm's publicly held financial information.

Mr. Cornwell then stated, that I had said the FDA since 1999 did not care about outcomes, in terms of injuries, complaints and failures. (See my response under Investigator's Remarks).

Mr. Cornwell then became visibly upset and stated that any adverse Warning Letters would do serious damage (to the firm).

Investigator's Remarks

I told Mr. Cornwell that either he perceived my comments made during the inspection differently than they were stated or that he mischaracterized my statements.

Specifically, I reminded him that the conversations we had regarding collecting quality data such as reworks and rejects was directed toward helping Mr. Cornwell understand the importance of those data. I did not tell Mr. Cornwell that the firm's losses were spiraling out of control.

I told Mr. Cornwell that if he did not agree on the need to collect quality data from a QSR point of view, that from a business point of view, collecting the data helps control costs and may be helpful to the firm.

Mr. Cornwell stated that he knows what good business is.

Further, I stated that Mr. Cornwell mischaracterized my comments about complaints as, FDA does not care about complaints.

What I told Mr. Cornwell was that FDA looks at a systems approach, and one of the systems that is looked at is complaints (under CAPA), but it is not the only system that is looked at.

I do not make a generalization about how the firm is operating based solely on my review of the firm's complaints.

I told Mr. Cornwell that the QSIT approach also requires us to look at Design Control, Management Controls and Process Controls.
While complaints may or may not be indicative of what is going on in a quality system, it is not the only thing that we (Investigator's/FDA) look at in making an evaluation.

NOTE: At this point, Mr. Cornwell stated, "This is not a quality issue." While making the statement, Mr. Cornwell picked up the Intran switch he had brought into the close out for demonstration, and threw the switch across the table in my direction.

(Tape 3, Side 2, Exhibit 70)

I told Mr. Cornwell that we use sampling tables to help the reviewer make a decision on the significance of the Observations.

I explained that I make the observations but that I do not control the outcome of the inspection. The outcome of the inspection is to be determined by individuals in compliance, the Centers and ultimately by individuals in the Office of Chief Counsel.

I assured Mr. Cornwell that FDA has numerous checks to assure that the investigator made valid Observations and that if anyone above me disagreed with my Observations, I would be so informed.
Mr. Cornwell asked if I had annotated the 483 with any of the firm's comments. I told him that the firm's comments would be noted in the Discussion with Management section of the EIR.

I explained that annotations on the FDA-483 are limited to, "corrected but not verified"; "corrected and verified"; "correction promised by"; and "no comment". I explained that due to the differences of opinion regarding the Observations, none of these annotations was applicable.

I told the firm that I had to defend my Observations through documentation. That documentation along with the firm's response to the Observations would be used by Compliance in making a decision on the outcome of the inspection.
I explained that it is not my job to go into a firm and find something wrong. I explained that it is my job to do an inspection, make observations, report the observations to the firm and to report them factually in the EIR.

I told the firm that I could not instruct them to respond in writing to FDA within fifteen days but that it might be helpful.

Mr. Pilot wanted to know if my EIR would be completed in fifteen days. I told him I had less than fifteen days to complete the EIR to stay within our policy for timeliness of review.

Mr. Pilot wanted to know if it was "normal" for me to have a deadline in which to complete my EIR. I explained that we have a policy for timely reviews.

Mr. Pilot wanted to know if I was specifically instructed, for this inspection, to get the report done within fifteen days. I told him that I had no specific instructions for this inspection and that I was following routine, District policy.

Mr. Pilot wanted to know if my findings had been influenced by my conversations with Mr. E. Smith and Ms. Regina Barrell.

I told Mr. Pilot that my findings were not influenced by anyone. Further, I told Mr. Pilot that I made my findings independently then shared those Observations with Mr. E. Smith and Ms. Barrell for discussion.

Mr. Pilot asked if it was normal procedure to have the FDA-483 reviewed by Compliance.

Mr. E. Smith stated that it is not unusual in the case of a follow-up to a Warning Letter or some other type of an action.

I told Mr. Cornwell that I was required to inform him of the remedies available to FDA to ensure compliance. I told Mr. Cornwell that the remedies available may include, Warning Letters, injunction, seizure, civil money penalties and in extreme cases criminal prosecution.

I told Mr. Cornwell that any of the remedies may be taken, at any time, without prior notice and do not have to be taken in order of severity.

Mr. Cornwell had no questions regarding the remedies available to FDA.

Mr. Cornwell could make no statement regarding corrective action or timeliness of corrective action, without first reviewing the information in the close out discussions and the items covered during the inspection.

It should be noted that I had informed Mr. J. Smith that I would be collecting the unofficial copies of the FDA-483 used during the discussions, at the end of the meeting. Mr. Cornwell had taken many notes on his unofficial copy and retained that unofficial copy at the end of the close out.

I explained that the official copy of the FDA-483 is the signed original that I provided to the firm.

Mr. Cornwell had no further questions or comments. The tape recording was stopped and the close out meeting was concluded.

Items Referenced in the Close Out Meeting but Not Discussed with Management

1) Regarding Mr. Cornwell's comments that the MDRs filed within the last year were contributed to clinician error, the findings in the MDRs do not come to the same conclusion.

The MDRs are provided as Attachments 1A-1C, and were retrieved from FDA's Maude database. The FDA database of these MDRs accurately reflects the information contained in the firm's MDR files, which I reviewed.

The MDR's were filed due to patient injury. The reports were 1) leaking from damage, 2) leaking from a cracked hub, and 3) breakage of the catheter in the patient.

The MDR reports do not state that the incidences were attributed to misuse of the device by the clinician.

2) Both during the inspection and the close out meeting, Mr. Cornwell complained that the inspection strained the resources of the firm and challenged the firm's ability to stay in business.

During the inspection I reminded Mr. Cornwell that aside from the close out meeting, I had only spent five days physically in the firm. I explained to Mr. Cornwell that I did not feel that five days was an inordinate amount of time to conduct a follow up inspection.

VOLUNTARY CORRECTIONS

The previous inspection of 6/4-6/8/01 resulted in a seven item FDA-483 being issued. The previous FDA-483 is included as Attachment 4.

The firm's procedure for Corrective and Preventive Actions now contains a section on what quality data sources will be analyzed (Attachment 4, FDA-483 Items 1a-b). However, some sources of quality data are still not included, such as Internal Audits and Unscheduled PM.

The Device Master Record has been corrected to reflect the correct specifications for [redacted] (Attachment 4, FDA-483 Item 2a).

The in process tests are now being documented although the documentation is not accurate (Attachment 4, FDA-483 Item 2b) (Current FDA-483 Item 4.2)

The [redacted] process, which was not validated, has been [redacted] (Attachment 4, FDA-483 Item 3). The validation of the [redacted] process is questionable (Current FDA-483, Item 7C).

The NCMR procedure has been corrected with respect to FDA-483 Items 4a-b (Attachment 4). However, there are still issues with the procedure (Current FDA-483 Item11).

The firm has eliminated the use of electronic signatures (Attachment 4, FDA-483 Item 5).

SAMPLES

Documentary sample, DOC 156363 was collected to demonstrate interstate commerce. On the advice of counsel, Mr. Cornwell did not listen to, review, or sign the Affidavit associated with this sample.

See "Further Discussion with Firm Management" section of this EIR for more explanation.

EXHIBITS

1A-1TT. Product Catalogs (Bound)
2. Complaint Listing Report [redacted]
3. Complaint. [redacted]
4. Compliant [redacted]
5. Complaint [redacted]
6. Complaint [redacted]
7. Complaint [redacted]
8. Complaint [redacted]
9. Complaint [redacted]
10. Complain[redacted]
11. Compliant [redacted]
12. Complaint [redacted]
13. Complaint [redacted]
14. Complaint [redacted]
15. Memo, [redacted]
16. Memo, [redacted]
17. Test Protocol, [redacted]
18. Test Report, [redacted]
19. 510(k) submission, 11/27/95 (6 pp.)
20. Test Protocol. [redacted]
21. Test Report [redacted]
22. Memo, [redacted] Sterilization Withstand Qualification (1 p.)
23. Memo, [redacted] IUP Biological Effect Testing (2 pp.)

24. Product Development Directive for
25. Regulatory Letter to file re:
26. Test Protocol fo)
27. Test Report for
28. This exhibit was discarded as duplicate of Ex. 27
29. Project Manager's Checklist for
30. Complaint spreadsheets
31. CPAR
32. QA Procedure for Customer Complaint System
33. Complaint
34. CPAR
35. Molding Set Up Sheet
36. DHR
37. DHR select pages
38. DHR , select pages
39. Procedure, Injection Molding
40. DHR select pages
41. DHR , select pages
42. Procedure, Intran Plus Test
43. DHR select pages
44. DHR select pages
45. Form
46. DHR , select pages
47. Procedure, Work Order Operation Tracking Form
48. Procedure, Testing for
49. Procedure,
50. Procedure, IUP Final Tester
51. Procedure, Catheter Final Inspection
52. Procedure, Preventative and Unscheduled Maintenance
53. Preventative Maintenance Meeting
54. Unscheduled maintenance report ((54.4 inadvertently omitted)
55. Test Report,
56. Procedure, Change Proposal
57. Device Master Record, IUP line (57.7 inadvertently omitted)
58. Change Proposal , dated
59. Complaint
60. Complaint
61. Procedure, Corrective/Preventive Action
62. Procedure, Internal Audit Procedure
63. Procedure, Nonconforming Materials
64. NCMR report
65. Procedure, Internal Audit Training Program
66. Audit schedule
67. Procedure, Receiving Inspection (
68. Procedure, Document and Data Approval

69. Product Labeling (See product sheets included after each section of labeling)
70. Audio Tapes of Close Out meeting conducted 4/15/02 (1 envelope of 3 original tapes (DEN-DO), or five duplicate tapes (CDRH/SLC-RP)

ATTACHMENTS

1A-1C. MDRs from MAUDE
2. FDA Guidance Document, "Deciding When to Submit a 510(k) for a Change to an Existing Device", select pages (5 pp.)
3. FDA Guidance Document, "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices 5/1/95 (G95-1)" (7 pp.)
4. FDA-483 dated 6/8/01

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