Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
CFN/FEI: 1718873
EI: 6/4-8/01
Thai Duong, Investigator

SUMMARY OF FINDINGS

Inspection of this medical device manufacturer was conducted as a routine DEN-DO, FY-01 workplan assignment in accordance with C.P. 7382.845, Inspection of Medical Device Manufacturers. Based on the current inspectional strategy, this inspection was conducted as a level 1 abbreviated QSIT inspection (Corrective and Preventive Action plus one additional sub system). The firm manufactures various Class II products in labor and delivery/obstetrics, neonatal intensive care, gynecology/urology/electrosurgery and blood pressure monitoring.

The previous inspection of this firm was conducted on 9/11-16/98 as a follow-up to a warning letter issued on 8/15/95. In addition, the inspection was also conducted in accordance with DEN-DO assignment, based on a request from CDRH to determine the cause of the adverse events associated with firm's Intrauterine Pressure monitors. The inspection revealed no significant deficiencies, and no FDA-483 was issued. However, a few specific GMP issues were discussed. The inspection was classified NAI.

The current inspection found the firm to have new and continuing deviations from the CGMP/QS regulation. These deviations include deficiencies in: corrective and preventive actions; device history records; process validation; non-conforming material records; electronic records and signatures; and sampling plans.

At the conclusion of the inspection, an FDA 483, Inspectional Observations, was issued to and discussed with Kevin L. Cornwell, President and CEO, as well as with John R. Smith, Quality Manager, and [redacted], Quality Supervisor. No comments were made to the items as noted on the annotated FDA 483 and the firm promised a written response to the items within fifteen days.

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

Sample DOC 50263 of PVC White IUP Molding Compound, IUP-400, lot # 72977, was collected to document Utah Medical Products' receipt of a component and its interstate shipment of a finished device from this facility.

HISTORY OF BUSINESS

Utah Medical Products was incorporated in the State of Utah in 1978. A copy of the 2000 Annual

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Report is attached as exhibit #1. The inside cover of the last page contains a listing of Board Members and Corporate Officers. The firm's Corporate Officers include: Kevin L. Cornwell, President and Secretary; Paul O. Richins, Vice President and Chief Administrative Officer; Greg A. LeClaire, Chief Financial Officer; and Mark A. Lanman, Vice President Sales.

According to the firm, the annual sales of Utah Medical Products are approximately [redacted]
The firm sold approximately [redacted] of the products out of the State of Utah. Utah Medical Products is currently registered with FDA as a medical device manufacturer and an initial distributor.

Utah Medical Products has [redacted] additional manufacturing facilities. The [redacted] facilities are located [redacted]

Responsible individuals present during the inspection are as follows:

Kevin L. Cornwell – President and CEO
John R. Smith – Quality Manager
[redacted] – Quality Supervisor

See exhibit #2 for a copy of the firm's organizational chart.

The facility occupies a large building located at 7043 South 300 West. There currently is a total of [redacted] employees. The firm's office hours are 7:00 a.m. – 5:00 p.m., Monday through Friday. The manufacturing area operates [redacted]

The firm manufactures and offers various Class II products in labor and delivery/obstetrics, neonatal intensive care, gynecology/urology/electrosurgery and blood pressure monitoring. The products include: Fetal Monitoring (the Intrauterine Pressure (IUP) Catheters); Vacuum-Assisted Delivery systems (the Vacuum Pump and Silicon Cups); Umbilical Cord Management (the Umbilicup and Cordguard); Disposable Pressure Transducer and Blood Sampling Systems for Critical Care Monitoring (Deltran line); Electrosurgical generators (Finesse line); Gynecology Electrodes (C-LETZ Conization Electrodes); Neonatal and Pediatric Intensive Care (the Umbili-Cath, Catheterization Tray, Nutri-Cath, Myelo-Nate, Uri-Cath, Picc-Nate, Hemo-Nate, Dialy-Nate, Thora-

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Cath, Pala-Nate, and Disposa-Hood); Endometrial Suction Curette (the Endocurette); Lumin Uterine Manipulator; Physician Controlled Irrigation (the Pathfinder Plus-Bulb Iirrigator); and Pelvic Floor Stimulation (the Liberty line).

The firm's product catalogs are attached as exhibit #3. A list of all 510(k)s the firm currently holds is attached as exhibit #4.

The 1995 inspection covered the manufacturing of the Intran IUP-400, Intrauterine Pressure Catheter. This device is used in high risk births. Review of complaints files revealed Intran IUP-400 Catheters which failed to meet electrical performance specifications for Unbalance. The firm did not recognize these performance failures and failure investigations for Unbalance were not conducted. Failure investigations did not include sufficient testing to determine if the device met all original release criteria. Failure investigations did not always include actual test data when testing was conducted.

The firm was found to be manufacturing and releasing Intran devices which did not meet the performance specifications contained in the 510(k) and Device Master Record. QA procedures contain test release criteria that were in conflict with the Device Master Record. QA test procedures were not being followed.

Device Master Record for the IUP-400 contains performance specifications, electrical specifications and usage environment specifications. Finished device testing consisted of Periodic testing was not being performed to demonstrate that IUP-400 Catheters met all applicable device specifications. The last documented qualification of the entire IUP-400 system was conducted in This inspection was classified OAI and a warning letter was issued on 8/15/95.

The previous inspection of this firm was conducted on 9/11-16/98 as a follow-up to a warning letter issued on 8/15/95. In addition, the inspection was also conducted in accordance with DEN-DO assignment, based on a request from CDRH to determine the cause of the adverse events associated with firm's Intrauterine Pressure monitors, IUP product line. At the time, a review of the OSCAR data base revealed events reported industry wide for this type of product. of these adverse events involved Utah Medical IUP's including deaths and injury in deaths and injuries from No deaths were reported for the other firms. This inspection revealed no significant deficiencies, and no FDA-483 was issued. However, a few specific GMP issues were discussed. The inspection was classified NAI.

The current inspection also covered the Intran IUP-400 product. The inspection found the firm to have new and continuing deviations from CGMP/QS regulation. See INSPECTIONAL APPROACH section below for more detail.

PERSONS INTERVIEWED & INDIVIDUAL RESPONSIBILITY

On 6/4/01, credentials were shown and FDA 482, Notice of Inspection, was issued to John R. Smith, Quality Manager, the most responsible individual at the firm by his own admission. Mr. Smith accepted the FDA 482 and introduced me to [redacted] Quality Supervisor. Mr. Smith and [redacted] accompanied me during the entire inspection and provided information and documentation for various activities.

Mr. Kevin L. Cornwell, President and CEO, was not available at the time of the issuance of the FDA 482. Mr. Cornwell was only present during the last day of the inspection to accept the FDA 483, Inspectional Observations.

On 6/8/01, an FDA 483 was issued to and discussed with Mr. Kevin L. Cornwell, as well as with Mr. John R. Smith, and [redacted] No comments were made to the items as noted on the annotated FDA 483 and the firm promised a written response to the items within fifteen days.

Mr. John R. Smith has been delegated the responsibility for quality assurance including GMP compliance since [redacted] of this year. Prior to becoming the Quality Manager, he spent [redacted] with the company as a [redacted] Mr. Smith stated that his responsibilities include management review, complaints and failure investigations, MDRs, and 510(k) submissions. He is also in charge of the Quality Group. In addition, Mr. Smith is responsible for the compliance activities for the [redacted] Mr. Smith is the firm's management representative and he reports directly to Mr. Cornwell.

[redacted] as a Quality Supervisor. She was the Quality Manager at [redacted] before joining Utah Medical Products. [redacted] is responsible for corrective and preventive action system, document control, hazardous materials, environmental monitoring, non-conforming materials, and internal audits. Mr. Smith stated that the firm hired [redacted] to help him with the quality assurance duties. She reports directly to Mr. Smith.

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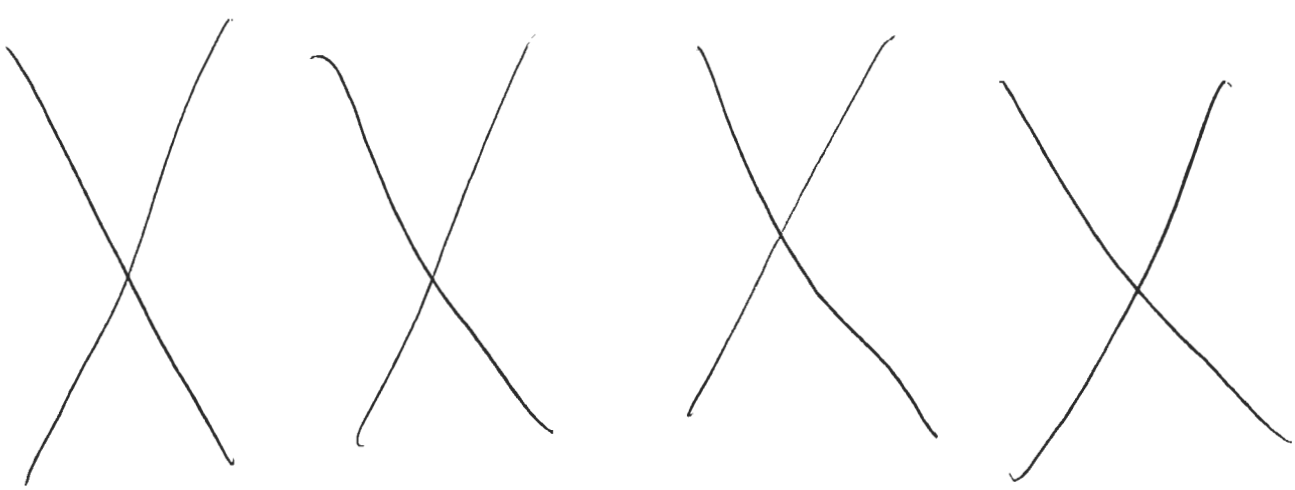
OPERATIONS

The facility occupies a large two-story building located in a business park with a total of approximately square feet.

The firm manufactures and offers various Class II products in labor and delivery/obstetrics, neonatal intensive care, gynecology/urology/electrosurgery and blood pressure monitoring. The firm's product catalogs are attached as exhibit #3.

The firm's manufacturing areas are divided The main manufacturing areas are described as follow:



The firm's floor plans are attached as exhibit #5.

Utah Medical Products, Inc. sends products after packaging

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INSPECTIONAL APPROACH

Review of the firm's complaint matrices (exhibit #6) revealed the firm received a total of 482 complaints from [redacted] The Intran product line received [redacted] complaints [redacted] Therefore, the Intran IUP product, specifically the IUP-400, was chosen for coverage during this inspection.

In contrast to the complaints received above, the firm was only able to identify [redacted] Intran complaints from the Complaints by Failure Type matrices. Of the [redacted] complaints, [redacted] of the complaints were identified having problems with [redacted] These are confirmed complaints regarding the [redacted] problem. The unit would drift when the drift test with the tip placed in water is performed. In those cases, the adhesive application was insufficient to prevent the liquid penetration into electrical connections of the chip. When liquid contacts the electrical connections, it gives the appearance to the monitor of a high unbalance.

The firm was found to be manufacturing and releasing Intran IUP-400 devices which do not meet the product specifications contained in the Device Master Record. See objectionable condition #2 below.

Similar to the 1995 inspection, the Device Master Record for IUP-400 contains [redacted] Finished device testing consists of [redacted] No periodic testing is being performed to demonstrate that IUP-400 meets all applicable specifications. Specifically, the drift test is not being performed periodically to show the device is capable of meeting its established performance specification. Note, the drift test is considered a destructive test, and therefore, it is not part of the final test. However, the firm has yet to validate the process to determine whether the adhesive application process is capable of producing products/results meeting its predetermined specifications, in lieu of routine testing. See objectionable condition #3 below.

Per the CAPA subsystem, complaints and in-process non-conformance records were the quality data sources selected to be reviewed during the inspection. The objectionable conditions found are documented and explained below.

Part 11, electronic records and signatures, was also covered during this inspection. Electronic signatures are being used in the complaint and incoming inspection systems. See objectionable condition #5 and 6 below.

PROMOTION AND DISTRIBUTION

The firm ships approximately X of its products in interstate commerce via X X X X. Promotion and distribution of the firm's products to customers are conducted through sales representative and trade shows. See exhibit #3 for the firm's promotional literatures.

SAMPLES COLLECTED

Sample DOC 50263 of PVC White IUP ———— IUP-400, lot # 72977, was collected to document Utah Medical Products' receipt of a component and its interstate shipment of a finished device from this facility.

REFUSALS

No refusals were made.

OBJECTIONABLE CONDITIONS

The following is a listing of the items contained on the FDA 483 and any discussion regarding them.

1. Review of the firm's corrective and preventive action system revealed:

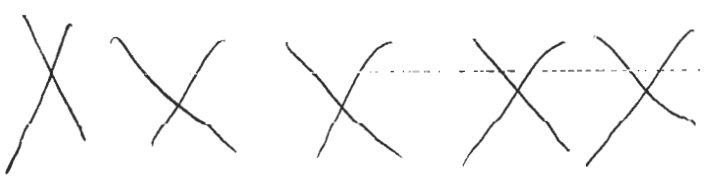
    a) Corrective and Preventive Action procedure, X , X , does not include the requirement for analyzing sources of quality data to identify existing and potential product and quality problems.

Discussion: The firm's Corrective/Preventive Action procedure X X Rev. X exhibit #7, does not address the requirement for analyzing sources of quality data to identify existing and potential product and quality problems. The procedure begins with an initiation of the corrective and preventive action request. There is no discussion of the sources of quality data to be analyzed.

    b) Not all quality data are being analyzed to identify existing and potential product and quality problems. For example: in-process rejects and MDRs.

Discussion: Although the firm's Corrective/Preventive Action procedure [illegible] Rev. [illegible] exhibit #7, does not include the requirement for analyzing sources of quality data, trending are being performed on certain quality data. The firm has yet to identify all sources of quality data to be analyzed to detect product and quality problems that may require corrective/preventive action.

The firm currently trends the following:

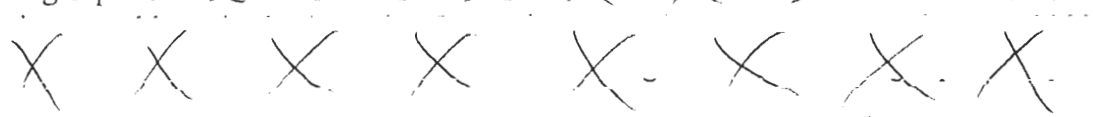


Complaint data are provided in a matrix form (see exhibit #6). The total number of complaints received is captured on a [illegible] basis and the complaint failure codes are tracked on a [illegible]

There is no procedure addressing the above trending reports. In addition, examples of quality data not being trended include MDRs, in-process rejects, maintenance records, quality audits, etc.

At the conclusion of the inspection, Mr. Cornwell asked how does the firm determine whether they have identified all the quality data sources to be analyzed. I stated that the firm needs to look at their operations and identify the sources that provide quality data that may require corrective/preventive action. Examples of sources of quality data were given to Mr. Cornwell including the ones mentioned above.

c) There are no corrective and preventive actions taken for the problems identified in the trending reports. [illegible]



Discussion: The firm currently trends the following:

Complaint data are provided in a matrix form (see exhibit #6). The total complaints received are captured and the complaint failure codes are tracked on a

Although the above analysis reports identified unfavorable trends and problem areas, there are no documented evidence showing that any corrective or preventive actions have been taken to directly address the identified issues.

2. Review of the firm's Device History Records (DHRs) for the Intran Plus Cathethers, IUP-400 revealed the following:

a) Manufacturing Procedure Intran Plus and IUP-300 Final Tester, does not assure that IUP cathethers conform to all approved design specifications prior to acceptance. Device Master Record specifications for Unbalance are release of finished devices in the range of

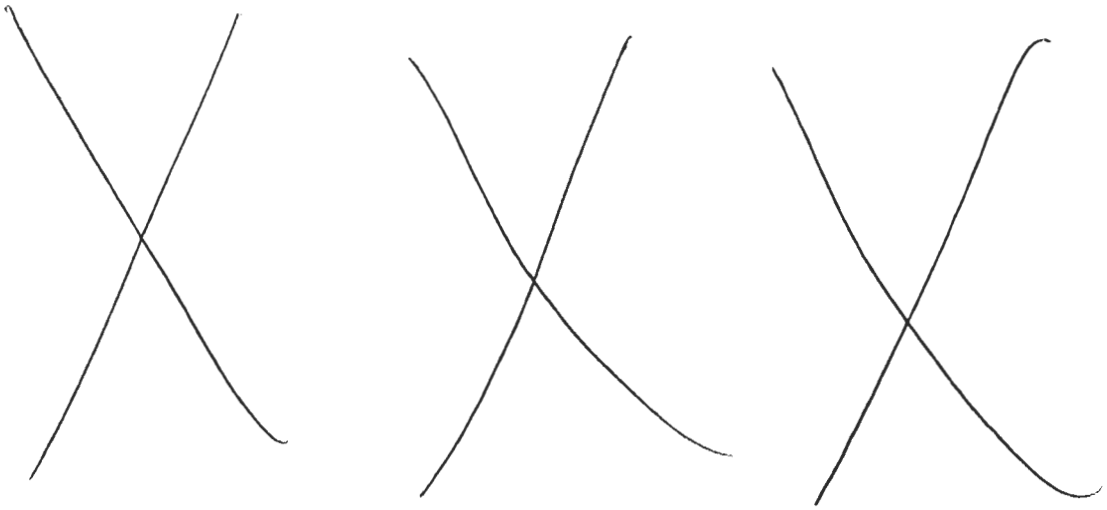
Discussion: The Device Master Record for the Intran Sensor Tipped Catheters, IUP-400, is attached as exhibit #9. The sensor specifications for Unbalance are

A copy of Manufacturing Procedure , Intran Plus and IUP-300 Final Tester, is attached as exhibit #10. Although it is not mentioned in the procedure, the final test is performed by The individual test results are The Summary Report for each lot is included with the Device History Record.

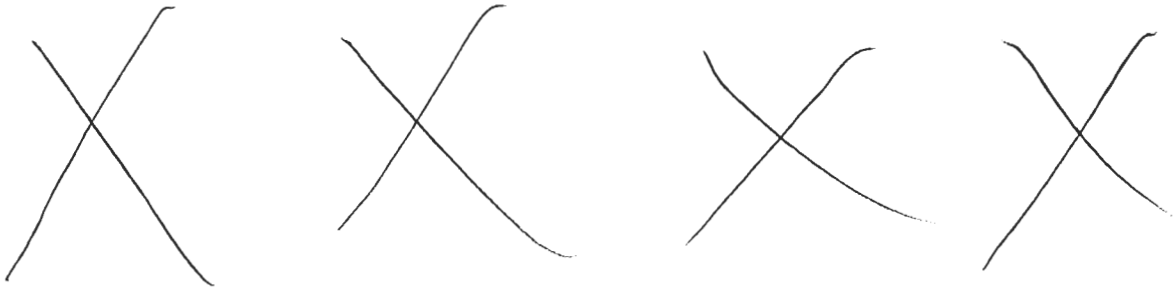
Review of the Device History Records, exhibit #12, revealed the specifications set for Unbalance are By following this procedure, the firm can accept a catheter with an Unbalance between which does not meet DMR specifications of

In the Summary Report, the firm no longer prints out the graphs of the results obtained from the

tests. However, some of the DHRs in year ~~X~~ do contain the summary graphs. The DHRs can be reviewed for the following information:



Discussion: A copy of the Work Order Traveler/Bill of Operations is attached as exhibit #11. The Work Order Traveler lists the various operations need to be performed. This include the following required tests:



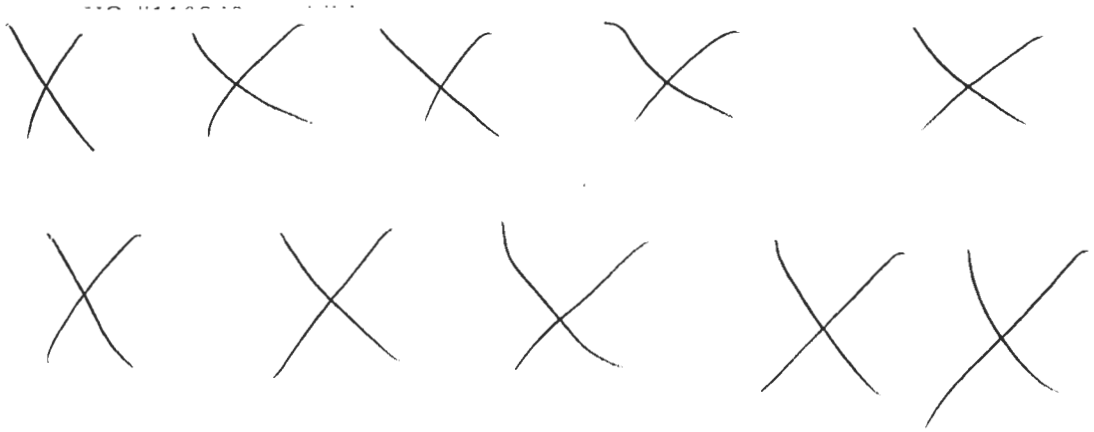
Review of the DHRs, exhibit #12, revealed that there are no documented evidence showing that the above tests are being performed. The Work Order Operation Tracking Form procedure, exhibit #18, requires the above tests be documented on the tracking form once the test is completed, but it allows the form to be discarded at packaging.

According to the firm, the purpose of the form is to allow the operators at packaging to verify that the tests were performed. Once the form is verified, the operator can get rid of it. I stated that I also need to know whether these required tests were performed, and the only way I can tell is by looking at the documentation.

c) Not all rejects are identified and documented. The devices failed during final test, documented in the Intran Plus Final Tester Summary Report, does not indicate its final disposition.

Discussion: Review of the firm's IUP-400 DHRs, exhibit #12, revealed that not all rejects from the lot are identified and documented. Specifically, the rejects from the required tests cited in the above item (2b).

Although the above tests are documented on the tracking form, the form does not include the quantity sampled, the quantity passed, and the quantity failed from each test. An example of the tracking form is attached as exhibit #19. In addition, examples from the DHRs collected to demonstrate the observation are as follow:



3. Validation studies have not been conducted for the manufacturing process of the Intran Plus products to determine whether the [redacted] process is capable of generating products or results meeting its predetermined specifications.

Discussion: The Device Master Record for IUP-400, exhibit #9, [redacted] No periodic testing is being performed to demonstrate that IUP-400 meets all applicable specifications. Specifically, the drift test is not being performed periodically to show the device is capable of meeting its established performance specification.

Note, the drift test is considered a destructive test, and therefore, it is not part of the final test. However, the firm has yet to validate the process to determine whether the [redacted] process is capable of producing products/results meeting its predetermined specifications, in lieu of routine testing.

A copy of the [redacted] procedure is attached as exhibit #16. [redacted] is applied to protect the electronic circuit. [redacted] An Intran device that fails a drift test means that the adhesive application is insufficient to prevent the liquid penetration into electrical connections to the chip.

4. Review of the firm's Non-Conforming Material system and reports revealed:

a) Non-Conforming Materials procedure, [redacted], does not include a determination of the need for an investigation.

Discussion: A copy of the Non-Conforming Materials Procedure, [redacted], is attached as exhibit #20. The procedure lacks the requirement to determine whether an investigation is needed after an evaluation of the nonconformance is performed.

[redacted] Non-Conforming Material Reports reviewed during the inspection, exhibit #21, show the lack of the determination of whether an investigation is needed for the reported nonconformance.

b) The Non-Conforming Materials procedure, [redacted], is not always being followed. For

example:

- Rework and Use As Is dispositions do not always include an assessment of the potential adverse effects (or lack thereof) on the quality of the final product.

- Use As Is dispositions do not always include the justification for the use of non-conforming products.

Discussion: Non-Conforming Materials procedure, in section (exhibit #20.6), states that

Conforming Materials reports revealed the following:

5. The firm has yet to certify to FDA that the electronic signatures in their systems are intended to be the legally binding equivalent of traditional handwritten signatures. Electronic signatures are being used in the complaint and incoming inspection systems.

Discussion: Electronic signatures are being used in the complaint and incoming inspection systems and the firm has yet to certify to FDA that the electronic signatures in their systems are intended to be legally binding equivalent of traditional handwritten signatures.

Mr. Smith stated that he was not aware of the requirement. I stated that the requirement for certification is in 21 CFR Part 11, Electronic Records; Electronic Signatures. This is not an approval process, but instead, it is a way to let FDA knows that the electronic signatures in their systems are intended to be the legally binding equivalent of traditional handwritten signatures.

A copy of a complaint report, exhibit #22, was collected to document this observation. The report shows the complaint record was closed by using the electronic signature

(exhibit #22.4).

During the inspection. [redacted] stated that the firm was having problems with printing out an incoming inspection record. Nevertheless, the firm was able to provide an example of the incoming inspection record from their computer system. A copy of the incoming inspection record is attached as exhibit #23.

6. For the electronic records and signatures, there are no procedures addressing the following:

a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

b) The ability to generate accurate and complete copies of records.

c) Protection of records throughout the record retention period.

d) Limiting system access.

e) And the system can create an audit trail that is computer-generated, time stamped to independently record the date and time of operator entries and actions.

Discussion: Electronic records and signatures are being used in the complaint and incoming inspection systems. The firm lacks procedures to address the requirements for electronic records and signatures set forth in 21 CFR Part 11.

Mr. Smith was not aware of the requirements in Part 11. He stated that the firm needs to look at the requirements for electronic records and signatures and see whether they can comply.

7. Sampling plans used are not always based on a valid statistical rationale. For example:

[redacted]

Discussion: The firm's sampling plans for incoming inspections and in-process testing are not always based on a valid statistical rationale. For example:

Incoming inspection procedure for Introducer, Break Away Needle, Metal, 2 French (Yellow), exhibit #24, requires inspection of [redacted] units for the various criteria regardless of lot size.

In-process inspection procedure for [redacted], exhibit #14, requires checking [redacted] to ensure that the [redacted]

DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, an FDA 483 was issued to and discussed with Mr. Kevin L. Cornwell, CEO, as well as with Mr. John R. Smith, Quality Manager, and [redacted] Quality Supervisor. No comments were made to the items as noted on the annotated FDA 483 and the firm promised a written response to the items within fifteen days.

Mr. Cornwell was informed that these items were not all inclusive and the firm is responsible for conducting audits and correcting any and all violations of the CGMP/QS regulation. I advised Mr. Cornwell of the sanctions available to FDA if corrections are not made, including warning letter, seizure, injunction, and prosecution.

ATTACHMENTS:

FDA-482 issued
FDA-483 issued

EXHIBITS:

1. 2000 Annual Report
2. Organizational Chart
3. Product Catalogs
4. 510(k) Listing
5. Facility Floor Plans
6. Complaint Matrices
7. Corrective/Preventive Action Procedure
8. Trending Reports
9. Device Master Record for Intran Sensor Tipped Catheters

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10. Intran Plus and IUP-300 Final Tester Procedure - X X
11. Bill of Operations – IUP-400 Intran Plus
12. IUP-400 Device History Records
13. Testing Tubing for Leaks Procedure - X X
14. Thread Wire Though Housing and Tubing Procedure – X X
15. Intran Plus Switch Plus Procedure - X X
16. Overmold Primer Application Procedure – X X
17. Overmold Process Procedure – X X
18. Work Order Operation Tracking Form Procedure
19. Work Order Operation Tracking Form
20. Non-Conforming Materials Procedure – ~~~
21. Non-Conforming Materials Reports
22. Complaint Report
23. Incoming Inspection Record
24. Incoming Inspection Procedure - Introducer, Break Away Needle, Metal, 2 French

Thai Duong,
Investigator