DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100	02/24/2003 - 03/12/2003* FEI NUMBER 1718873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kevin L. Cornwell, CEO and Chairman

FIRM NAME	STREET ADDRESS
Utah Medical Products, Inc	7043 South 300 West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Midvale, UT 84047	Medical Device

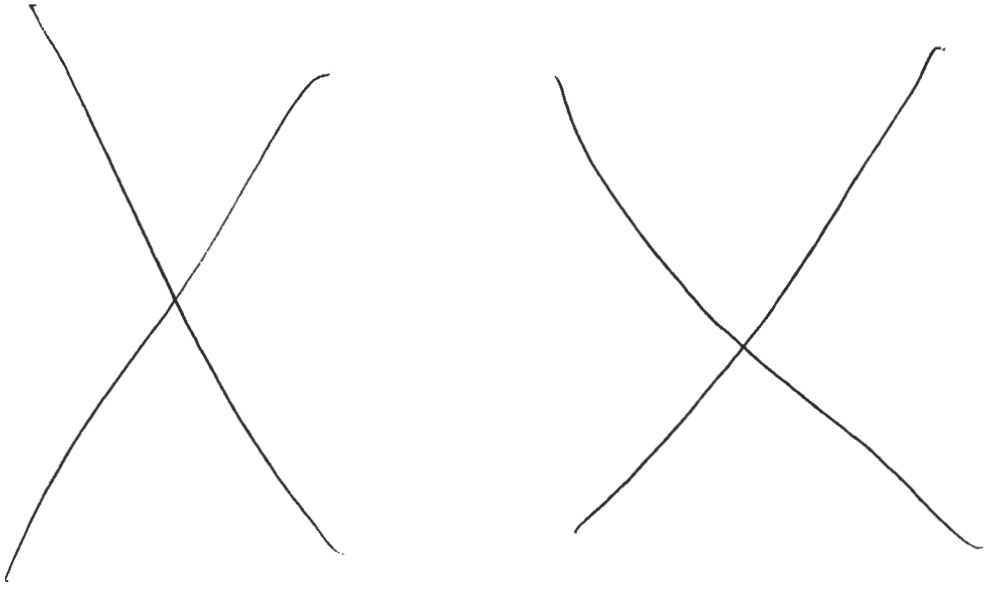
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

The observations noted in this Form 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 quality system requirements.

OBSERVATION 1

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

Specifically,



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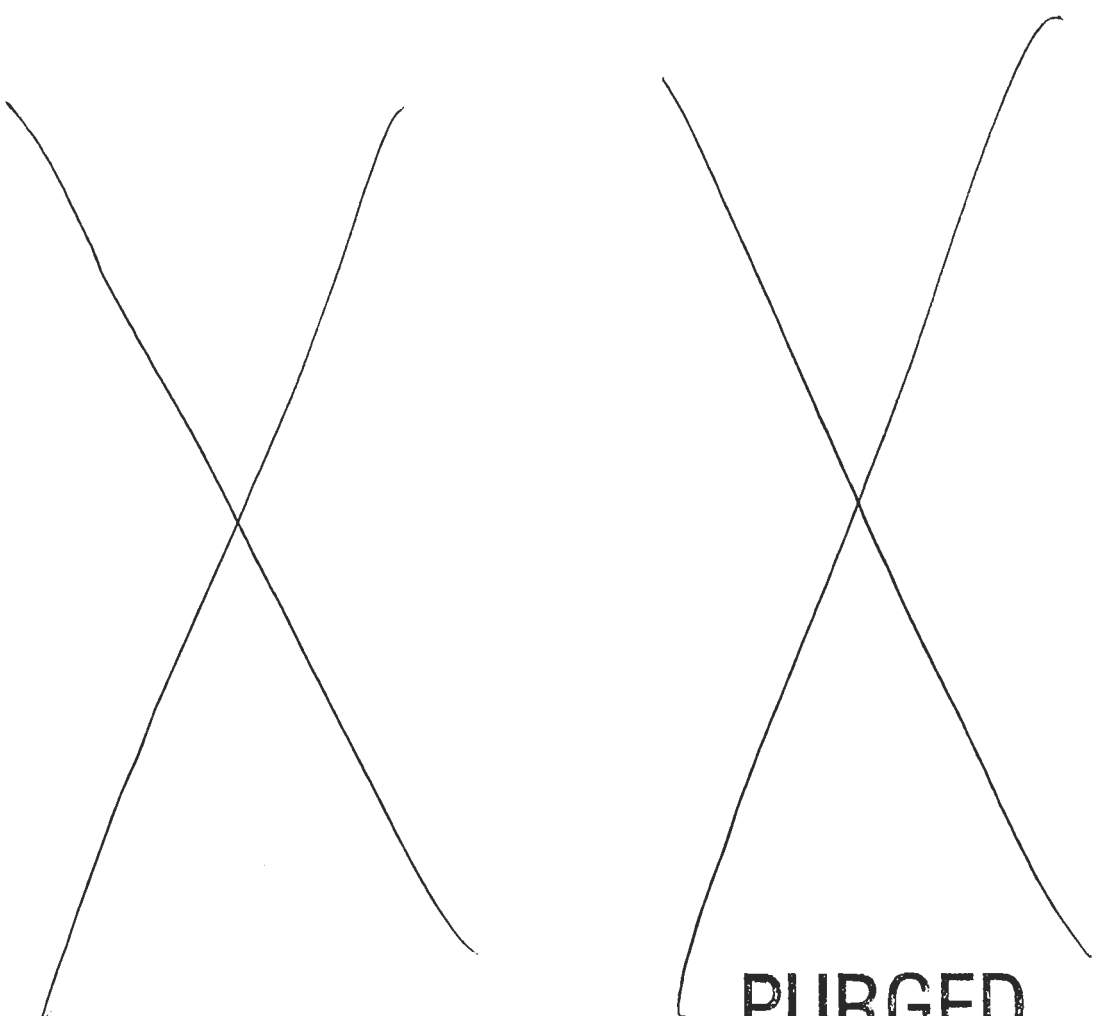

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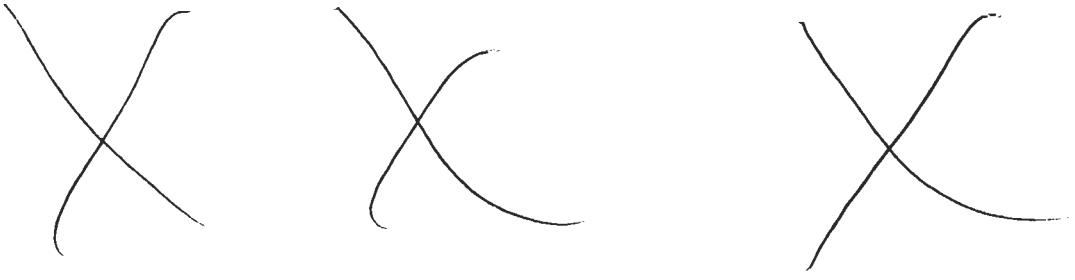

Annotation: 1.A.1. Under consideration.
1.A.2. Under consideration.

1.B. Under consideration.

1.C.1. Under consideration
1.C.2. Under consideration

1.D.1. Under consideration
1.D.2 Under consideration

1.E. Promised to correct in X

1.F.

OBSERVATION 2

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

Specifically,

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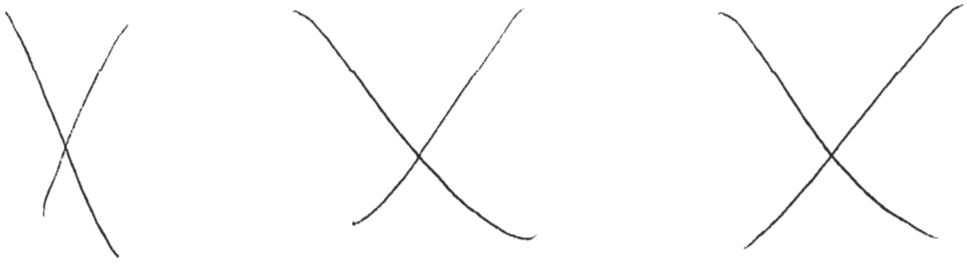
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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



Annotation: 2.

OBSERVATION 3

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

Specifically,

A. Regarding Finesse ESU complaints:

1. The Corrective and Preventive Action procedure and the Customer Complaint System procedure are inadequate with regards to the use of failure codes. They do not assure that codes will be uniformly applied as the procedures do not define each code or instruct when each code is to be used. The procedures do not include instructions for changing the codes after evaluation/investigation, nor do they include how this data will be collated and utilized. Review of similar complaints indicated different failure codes were assigned. For example, a review of 18 Finesse complaints in [illegible] and their failure codes revealed [illegible] complaints coded as failure code [illegible] had information describing components as [illegible] There were only 2 complaints coded as [illegible]

2. [illegible] Finesse [illegible] complaints that had output transistors replaced stated these were random failures. Complaint letter in [illegible] indicates this failure typically happens in older systems. This system was of the [illegible] The complaint summary for [illegible] received [illegible] shows the unit had only been in service since [illegible] complaints showed that units were not old; therefore, they may not be random failures and no corrective or preventive action was opened to evaluate this discrepancy.

3. [illegible] complaints had no evidence of complaint and service repair history reviews [illegible] And, [illegible] complaints had searches of the complaint history and/or service repair history only for the complaint unit [illegible] The Corrective and

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Preventive Action procedure is inadequate in that it does not define what type of history search, or to what extent the search should be conducted on complaints. Some complaints examine entire device families while other examine only the affected unit. Further, some complaints included having records reviewed for ; while others included having records reviewed for

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

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

D. The Corrective and Preventive Action procedure does not adequately describe when non-conforming incoming product should be evaluated or investigated nor when a corrective and preventive action should be initiated. For example, Non-Conforming Material Reports reviewed for the Intran Plus membrane switch for the failure, did not document the evaluation or investigation of the failure and no corrective or preventive action was initiated.

Annotation: 3.A.1. Under consideration
3.A.2. Under consideration
3.A.3. Under consideration

3.B.

3.C. Under consideration

3.D. Under consideration

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OBSERVATION 4

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

Specifically,

X complaints dated X were reviewed for cracking/brittle IUP catheters. The original CAPA, X was opened X and closed. X There is no documentation of evaluation of patient risk associated with this device failure, and no documentation that an evaluation was made to determine if other devices manufactured by the firm in a similar form or manner may experience a similar failure.

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

Annotation: 4.

OBSERVATION 5

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

Specifically, between X X X complaints accounting for 9 devices were confirmed for adhesion problems at the IUP X X resulting in device failure. There is no evidence that any corrective and preventive action has been documented or implemented for these complaints. Reduction in the number of complaints is not an adequate verification or validation that a corrective and preventive action is effective. Further, these complaints relate to the X gluing process, which has not been validated; therefore, there is no assurance that corrective and preventive action has been addressed in retraining.

OBSERVATION 6

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

Specifically,

A. A MedWatch report was made by a user facility on UTMD complaint X for failure of a Finesse Electrosurgical

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

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

OBSERVATION 7

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

Specifically,

A. X Rev XMicrobial Bioburden Testing of Devices is unclear, in that it,
1. does not state the required frequency of bioburden testing;
2. it does not state what actions to take when the "Results" show "Note B - Spreader" "count is considered a minimum estimate due to swarming of certain colonies on the membrane"; and,
3. lacks information on testing of caps, ports, and inner lumens of devices.

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

C. Procedure, X Environmental Control and Monitoring, is inadequate because,
1. there is no justification for not sampling water at the extruder when a previous test report X dated X found bacterial counts to be X X and,
2. it does not include a diagram of the compressed air system identifying points of use and justification for why there is only X sampling point.

D. Extruder procedures X Rev. X Extrusion Set-up, X Rev. X Extrusion Running Procedure and X Rev. X Extrusion Cleaning are inadequate due to the following observations made during extrusion molding on X
1. the upper cooling tray that tubing passes through had tan floating debris in it;
2. the lower cooling tray was uncovered, rusty, and had a film coating it. This water is recirculated for cooling tubing passing through the upper cooling tray;
3. the water control float had an empty cleaning bottle taped to it; and,
4. the take off conveyor was cracked with dark areas within the cracks.

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

1. on 2/27/03 the ESD continuous monitor used in association with the wrist strap in the room at the work station location was not visible to the operator, although the equipment was in use. On 3/6/03, the light was not visible; and,
2. on 3/6/03, the ESD continuous monitor in the room, at work station behind the work station and closest to the room exit corridor, was observed to be mounted below the table top such that an operator standing or sitting at the work bench could not see the system lights.

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

G. The Instrument Calibration Procedure, used by for calibration of the laser micrometer used in extrusion, does not require the technician to denote on the Certificate of Calibration which test method was used (Test Method 1 or Test Method 2).

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

OBSERVATION 8

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

Specifically,

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

1. As of 3/5/03, no blueprints or diagrams were available on the water system showing: piping throughout the firm, valve

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

locations, points of use, sampling points, mixing hookups, the water storage tank, no incoming water specification, and no extrusion water quality specifications.

2. There are specifications and no mixing records for water.

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

Annotation: 1-3. Under consideration

OBSERVATION 9

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

Specifically,

The Qualification of the Final Tester dated

a. does not include the use of devices with "known" defects to challenge the test equipment's ability to detect said defects;
b. does not define the acceptable value of standard deviations; and,
c. does not qualify the test equipment to test for defects, an attribute that the tester is currently being used to evaluate.

OBSERVATION 10

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

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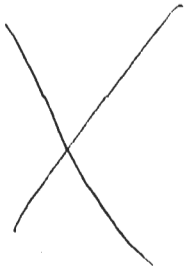
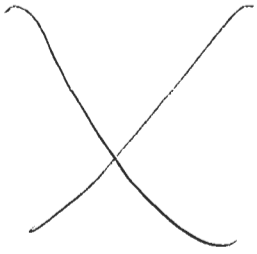
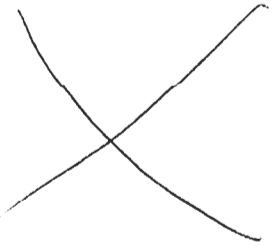

Annotation: 1. Under consideration
2.

OBSERVATION 11

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

Specifically,

A. Test Protocol, [illegible] IUP [illegible] Test used to qualify the [illegible] does not define what the acceptable [illegible] reading should be for the functionality test, rather the measured values are compared to one another for all devices tested. Therefore, the firm failed to have adequate procedures to ensure that design outputs met the requirements of design inputs.

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

1. which lots of finished product will be used in the qualification; or,
2. what the acceptable [illegible] reading should be for the functionality test; it only states what the acceptable deviation value is from baseline.

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

Annotation: 11.A. Under consideration
11.B. Under consideration

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OBSERVATION 12

Design validation did not ensure that devices conform to defined user/patient needs and intended uses.

Specifically,

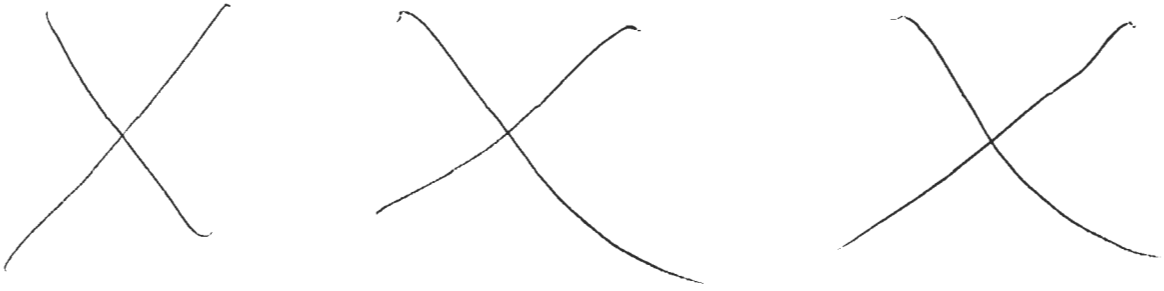
While the firm has performed accelerated aging testing for devices, real time shelf life testing has not been implemented to confirm the results of the accelerated aging testing. Therefore, there is inadequate design validation to support the firm's intended use of a five year expiration date specifically on X devices.

Annotation: 12. Under consideration

OBSERVATION 13

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

Specifically,



Annotation: 1.-2. Under consideration

OBSERVATION 14

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

Specifically,

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

Annotation: Under consideration

OBSERVATION 15

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

Specifically,

On 3/4/03, extrusion molding equipment was observed during operation with the following equipment modifications for use:

1. tape was observed at the exit of the upper water tray, around the back of the extrusion nozzle;
2. plastic tubing was attached to the l X X laser micrometer, and extrusion tubing was running over and in direct contact with the straw; and,
3. tape was used to attach extensions to the side guards on the take off conveyor X X X X

OBSERVATION 16

Schedules for the adjustment, cleaning, and other maintenance of equipment were not established and implemented.

Specifically,

A. There is no preventative maintenance plan for, nor documentation of, preventative maintenance being performed for the X aser micrometer used to measure tubing diameter on the extrusion line, although the instruction manual for the equipment calls for cleaning the windows , X X . The equipment was observed in use on 3/4/03.

B. The schedule for preventative maintenance of the X machine used in packaging IUP devices, was not complete in that it did not identify, specifically, all the areas of the equipment that require maintenance according to the equipment operator's manual. The PM does not refer to the operator's manual.

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

1. is not specific as to the areas of the mats that are calibrated;
2. which specific mats are tested on each , X PM;

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

D. Procedure Rev. dated , Section requires tacky mats located at various room entrances to be changed On 2/24/03 and 3/6/03 tacky mats were observed to be dirty, outside of cleanrooms and/or inside the room. There is no documentation that the tacky mats are being changed or whenever necessary as required by the procedure.

E. " Production Areas, Manufacturing Midvale" was not completed for the first of in the room, per , Housekeeping.

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

OBSERVATION 17

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

Specifically,

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

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Annotation: 17. Corrected but not verified

OBSERVATION 18

Documents were not reviewed and approved by the individual designated in document control procedures.

Specifically,

An untitled document being used for calibration of the ESD system, which begins as

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X , has not been made part of the controlled document system by review and approval.

Annotation: 18. Promised to correct within X

OBSERVATION 19

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

Specifically,

Procedure, X , Rev. X s not adequate to describe how the audit plan is to be developed to ensure effective coverage of objectives. There is inadequate description of how to develop the audit plan. For example, the Corrective and Preventive Action System audit examined X CAR, number X and a product recall, X only. This would not be enough information to determine the effectiveness of the firm's ability to meet all of the requirements of the corrective and preventive action system.

Annotation: 19. Corrected but not verified

*** DATES OF INSPECTION:**
02/24/2003(Mon), 02/25/2003(Tue), 02/26/2003(Wed), 02/27/2003(Thu), 02/28/2003(Fri), 03/03/2003(Mon), 03/04/2003(Tue), 03/05/2003(Wed), 03/06/2003(Thu), 03/12/2003(Wed)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Ricki A. Chase-Off, Investigator

Karen A. Coleman, Investigator

PACO 3/12/03

PURGED

SEE REVERSE OF THIS PAGE

DATE ISSUED
03/12/2003