DEPARTMENT OF HEALTH AND HUMAN SER. ICES
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	02/02/2004 - 03/03/2004* FEI NUMBER 1718873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kevin L. Cornwell, Chairman & CEO

FIRM NAME	STREET ADDRESS
Utah Medical Products, Inc	7043 South 300 West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Midvale, UT 84047-1048	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

For example,

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

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

c) The material drying process has not been qualified or validated. The drying process includes a) hour dry time at a temperature of degrees Fahrenheit (BOO Process Number , Operation Work order number dated) documented that material was dried at and degrees Fahrenheit between Work order number dated documented that material was dried between and degrees Fahrenheit between The material) specification sheet states , work orders (a total documented runs) were reviewed between for injection molded part

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SEE REVERSE OF THIS PAGE		DATE ISSUED
		03/03/2004

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d) The annealing process qualification associated with injection molded part is not complete in that data/documentation does not exist associated with

for the operations as follows:

the test. The current Bill of Operations (Process No. , Operation states to anneal parts to procedure . Manufacturing procedure entitled "HEAT ANNEALING PROCEDURE", Rev. , dated (section states to preheat oven to degrees Fahrenheit (section) and place trays in preheated oven for minutes (section

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

e) Bond qualification for the ' revision dhesive was last done or as part of Bond qualification for the rev. dated was last done ' as part of evision The firm was unable to provide data to demonstrate that these bond process qualifications support the current process.

f) There is no maximum time established for pre-extrusion drying of the used to mold the Assembly respectively.

OBSERVATION 2

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

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

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1) Work order number On and injection mold manufacturing (was documented as having) and points above the established UCL respectively.

2) Work order number : On and injection mold manufacturing ' was documented as having and) points above the established UCL respectively. NCMR dated documents that

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

OBSERVATION 3

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

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

For example,

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

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

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In addition, the data is imported into Spreadsheets from the Complaint Handling System to generate reports for the MRB Reviews including the reports such as the firm's Software Validation Master Plan schedule, updated on , indicates the Test Protocol is in the phase and designates the criticality as high for

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

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

3/3/04

OBSERVATION 4

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

Specifically, the Corrective and Preventive Action procedure, Document , Revision Revision Date does not define how data will be presented to the Materials Review Board (MRB), CAPA Committee, for effective analysis. For example:

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

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

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2. Complaint , dated for Electrical Surgical Unit , was assigned failure code however failure analysis revealed that the complaint , dated , for , was assigned failure code however failure analysis also revealed that the unit had no sound because

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

OBSERVATION 5

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

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

OBSERVATION 6

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

For example:

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

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

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

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

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

OBSERVATION 7

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

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

a) The following error was not detected during review and approval of Device History Record: Extrusion molding batch, product test samples for work order Assembly were selected by production personnel according to an obsolete sample scheme.

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

*** DATES OF INSPECTION:**
02/02/2004(Mon), 02/03/2004(Tue), 02/04/2004(Wed), 02/05/2004(Thu), 02/06/2004(Fri), 02/07/2004(Sat), 02/09/2004(Mon), 02/10/2004(Tue), 02/11/2004(Wed), 02/12/2004(Thu), 02/17/2004(Tue), 02/23/2004(Mon), 02/24/2004(Tue), 02/25/2004(Wed), 02/26/2004(Thu), 02/27/2004(Fri), 03/01/2004(Mon), 03/02/2004(Tue), 03/03/2004(Wed)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Lori A. Medina, Investigator

Ralph W. Jerndal, Investigator

Monica J. Wilkins, Investigator