DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center - Bldg. 20 P.O. Box 25087 Denver, CO 80225-0087 Phone: (303) 236-3000	6/4-8/01 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin L. Cornwell, CEO

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

DURING AN INSPECTION OF YOUR FIRM II (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.

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

a) Corrective and Preventive Action procedure, TD-QA-01, does not include the requirement for analyzing sources of quality data to identify existing and potential product and quality problems.

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

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

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

b) There are no documented evidence that the following required tests are being performed:

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.

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

PURGED

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		THAI DUONG, Investigator	6/8/01

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

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

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

- Reword 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.

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

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.

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

No Comments at this time

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		THAI DUONG, Investigator	6/8/01