DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, Bldg. 20, Denver Federal Center P.O. Box 250087, Denver, Colorado 80225-0087 303-236-3000	3/26/02-4/15/02
	FEI NUMBER 1718873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: **Kevin L. Cornwell, CEO and President**

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

DURING AN INSPECTION OF YOUR FIRM I OBSERVED

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.

1.1 In [redacted] the IUP line of devices underwent a change in catheter material from [redacted]. Validation review revealed the following:

A. There are no raw test data or a validation protocol for the [redacted] sterilization, which was approved for the devices;
B. There are no raw test data or a validation protocol for the [redacted] sterilization, which was approved for the device;
C. There is no evidence to support the five-year expiration date given to the devices.

1.2 In [redacted], the IUP product line was approved for a second exposure to [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.

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.

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.

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	Ricki A. Chase-Off	Ricki A. Chase-Off, CSO ~~Elvin R. Smith, SCSO~~ RACO 4/15/02	4/15/02

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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]

3.1 On [redacted] CPAR [redacted] was initiated in response to complaint [redacted] received on [redacted], which found that [redacted] IUP units returned for evaluation failed the [redacted] Test. Review of CPAR [redacted] found 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;

[redacted]

C. A review of the Device History Records (DHR) for the affected lots (111757 & 111758), which require [redacted] inspection for [redacted] 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.

[redacted]

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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] levice discrepancy. Further, from the Final Test [redacted] devices were accepted. However, only [redacted] devices were released to sterilization. There is no documentation of the 3 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] levice discrepancy.

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.

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

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	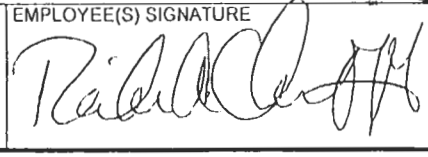	Ricki A. Chase-Off, CSO ~~Elvin R. Smith, SGSO~~	4/15/02

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A. Procedures [redacted], 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.

5. Not all significant quality data are being captured and reviewed in that,

A. Form [redacted] 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 [redacted] is discarded thus, information, which may be useful in a failure investigation is lost (i.e. who the inspector was).

6. Review of the firm's Preventative Maintenance program for equipment used in device manufacturing revealed that,

A. Procedure [redacted], 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.

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,

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A. Lot 111409 consisted of the manufacture of X component parts X , of that X devices were selected for sampling with no statistical rationale;
B. IUP lots are broken down into batches of X X for sampling purposes. The number of units sampled is always X There is no statistical justification for sampling X devices. (Lots 111757, 111758)
C. X X X X X X X

However, the process qualification failed to explain the statistical rational behind the selection of X test units used for the X X X X X

X X X X

8. Procedure X Change Proposals does not ensure that document changes are evaluated to determine the other areas of the quality system that may be affected by the change. For example, on X X for IUP devices was corrected to reflect a change in X X X X X X X However, device failure test specifications in complaints X X X X were not changed and remained at X X

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.

10. In reviewing procedure X Corrective/Preventive Action, it was noted that;

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A. The procedure does not require the following data sources to reviewed and/or analyzed

A. 1. X preventative maintenance, both scheduled and unscheduled
b. 2. Results of Internal Quality Audits

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	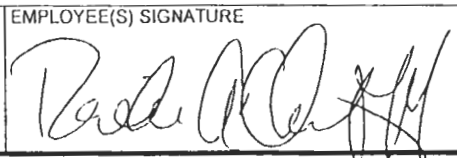	Ricki A. Chase-Off, CSO ~~Elvin R. Smith, SCSO~~ CAPA 4/15/02	4/15/02

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11. Procedure X 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.

12. The Internal Audit procedure X and the Internal Audit training program X 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.

13. Software systems are being used as an integral part of the Quality System. X

4/15/02

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.

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