



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region **94377d**

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

October 17, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James F. Wilson
President
Medi-Stat, Inc.
77 Deerwood Drive
Littleton, Colorado 80217

Ref. #: DEN-04-01

Dear Mr. Wilson:

During May 9 through 21, 2003, Investigator Nicholas R. Nance from the U. S. Food and Drug Administration (FDA), and Environmental Protection Specialist Vicki L. Smith with the State of Colorado Department of Health, conducted an inspection of your establishment in Lakewood, Colorado. The inspection revealed that your firm reprocesses various single use pulse oximeter sensor devices. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals.

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. Significant deviations include, but are not limited to the following:

1. Failure to validate a process with a high degree of assurance and approve the process according to established procedures, and failure to document the validation activities and result, as required by 21 CFR 820.75(a). For example, the following processes have not been validated:

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There is no documentation to demonstrate that the sterilization, application of plastic laminate, or the use of cleaning agents on the pulse oximeter sensors do not adversely affect the safety or operation of the devices.

There is no documentation to show the final testing used by your firm assures that the devices meet the original equipment manufacturers' specifications.

There is no documentation to demonstrate the number of times these devices may be subjected to multiple re-sterilizations and cleaning.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30. For example:

Your firm has failed to establish and maintain design control procedures to include design and development planning; design input; design output; design review; design verification; design validation; design transfer; design changes and creation of design history files. You have not established procedures to monitor the devices for any changes made by the original equipment manufacturers in the design, composition, or labeling of the devices, so as to change your processing steps, accordingly.

3. Failure to maintain complete device history records (DHR) to assure that each batch, lot, or unit is manufactured in accordance with the device master record (DMR), as required by 21 CFR 820.184. For example:

Our investigator observed an incomplete DHR that did not contain information regarding all the required processing steps, acceptance records or the approval signature. Also, there was no information concerning the label and labeling used in the manufacture of the specific devices.

4. Failure to establish and maintain procedures for quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, and failure to document the results of the quality audits, as required by 21 CFR 820.22. For example:

Your audit procedure does not address the areas to be audited, the audit frequency or the performance of re-audits, if necessary.

5. Failure to establish and maintain procedures to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes, is capable of producing valid results, and is routinely calibrated, inspected, checked and maintained, as required by 21 CFR 820.72. For example:

The operator's manual for the ~~XXXXX~~ recommends annual calibration in order to assure valid results. Your records that FDA inspected in May 2003 indicate that the last calibration occurred in ~~XXXXX~~. Also, there was no evidence of calibration or periodic

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maintenance for the ~~_____~~, used for final testing. The purpose of periodic calibration and maintenance is to assure that the results obtained are within acceptable limits. If the equipment used for testing is out of specification, all of the testing performed with that equipment must be questioned.

We are in receipt of your correspondence dated June 6, 2003 in response to the FD-483 issued at the conclusion of the inspection. Your response is inadequate for the following reasons:

With regard to validation, you state that your data base contains enough reprocessed pulse oximeter sensor information and history to validate your reprocessing process. However, your response does not include any raw testing data to justify this statement. In fact, our inspection disclosed that you do not record the actual test results for any devices you reprocess. Without such documentation, there is no evidence showing that the devices meet the original equipment manufacturers' specifications when they leave your facility. The database referred to in your response is strictly a ~~_____~~. Your Device Tracking Form shows how many devices were shipped and although it may indicate the number of failed devices, it does not indicate the cause of the failures, or if you conducted any investigation as to the reason for the failure. Your response also indicates that you perform ~~_____~~ testing of all pulse oximeter sensors but, again, you do not document the actual test results. Without documentation of the results, there is no evidence that testing is performed.

The Quality Audit Procedures you propose in response to Observation 2 state that you will perform audits on an annual basis, ~~_____~~. "An audit implies that you will evaluate an entire system or process, not just an isolated action as you did in response to the Device Tracking Form for ~~_____~~. What you performed is more appropriately called a corrective action, taken in response to a deviation from standard operating practices. There is no evidence that you reviewed all the Device Tracking Forms to determine if there were any similar deviations. It is unclear from your Quality Audit Procedures how a problem within your reprocessing system will be identified or what constitutes an appropriate audit. Also, there are no scheduled dates listed for the performance of the audit, nor are there criteria listed in order to define the successful completion.

The Device Master Record you submitted is inadequate. A Device Master Record is specific for each device and must include or refer to the location of the following information: a.) device specifications, including appropriate drawings, composition, formulation, component specifications and software specifications; b.) production process specifications including the appropriate equipment specifications, production methods, production procedures and production environment specifications; c.) quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used; d.) packaging and labeling specifications, including methods and processes used; and e.) installation, maintenance and servicing procedures and methods. The Device Master Record you submitted is inadequate in that it does not specifically contain all of the required information listed above for each type of oximeter sensor you reprocess. The Device History Record you attached is also inadequate in that it does not

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would follow up with the Director within 30-60 days to define the specifics of your appeal. To our knowledge, we have not received such an appeal.

Your promotion and introduction into interstate commerce of the oximeter sensors render them adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

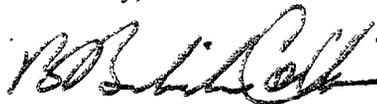
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, FDA will not approve an application for premarket approval for Class III devices to which the Quality System regulation deficiencies are reasonably related until the violations are corrected. Also, no requests for FDA export documents will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,



B. Belinda Collins
District Director

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