



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
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6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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December 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary Gelman
President and Chief Executive Officer
Misonix, Inc.
1938 New Highway
Farmingdale, New York 11735

Ref. #: DEN-02-08

Dear Mr. Gelman:

On October 3 through 19th, 2001, Investigator Nicholas R. Nance of our office conducted an inspection of Sonora Medical Systems, Inc. located at 2021 Miller Drive, Longmont, Colorado. Our investigator determined that your firm manufactures various diagnostic ultrasound transducers and refurbishes diagnostic ultrasound systems and accessories. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Failure to conduct management reviews to determine the suitability and effectiveness of the quality system, as required by 21 CFR 820.20(c). For example, not all sources of quality data are reviewed, tracked or trended by management, such as Discrepant Material Reports (DMRs) or Corrective/Preventive Action Reports (CARs).
2. 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 document the results of the quality audits, as required by 21 CFR 820.22. Reaudits of deficient matters are not taken. For example, audit schedules show that various elements of the Quality System have not been audited annually,

Sonora failed to adequately conduct a quality review of the device history records in that devices with incomplete and incorrect records were approved and released for distribution. Procedures do not contain sufficient information or criteria to define when devices pass inspection, i.e. test techs performing ARS transducer testing use subjective visual evaluation of the test results to determine when a probe passes or fails.

9. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained, as required by 21 CFR 820.72(a). For example, records reviewed for test equipment used in the manufacture of probes were found to either not be on a calibration schedule, showed no evidence of calibration or had not been calibrated within the timeframes required by your procedures.
10. Failure to develop adequate validation procedures to assure specified requirements are met, as required by 21 CFR 820.75(a). For example, there is no approved validation protocol to justify the validation test report for the automated Probe Tester or the automated ~~XXX:XX~~ temperature tester. Also, there was no evidence that the ARS probe PROM programming procedure and the work instructions for testing probe surface temperature have been validated.

The above identified deviations are 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 Federal 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. A copy of the FDA-483 is enclosed for your information. 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, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

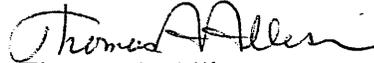
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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.

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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,



Thomas A. Allison
District Director

Enclosure

Cc: Mr. G. Wayne Moore
President and CEO
Sonora Medical Systems, Inc.
2021 Miller Drive
Longmont, Colorado 80501