



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/769-3010

WARNING LETTER

VIA FEDERAL EXPRESS

Our ref: 2916737

December 11, 1998

Robert L. Mathews
General Manager
Diasonics Ultrasound, Inc.
2860 De La Cruz Blvd.
Santa Clara, CA 95050

Dear Mr. Mathews:

Your firm was inspected between September 19 through 29, 1998 by Investigator Sally O. Lum, California Department of Health Services, Food and Drug Branch, under contract with the U.S. Food and Drug Administration (FDA). Investigator Lum, operating under the authority of the Federal Food, Drug, and Cosmetic Act, focused her inspection on the manufacturing of ultrasound probes. These products are medical devices as defined by Section 201(h) of the Act.

The 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, packaging, storage, or installation are not in conformance with either the Good Manufacturing Practice Regulations (GMPs) or the Quality Systems Requirements (QSRs) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820. We acknowledge receipt of your correspondence dated October 14, 1998 to this District, which was made in response to the inspectional findings. The following list of violations includes our assessment of the adequacy of some of the corrective measures which you described in your correspondence.

1. You have failed to ensure that Quality Systems Requirements are established and effectively maintained, as evident by the deficiencies noted during the inspection. Deficiencies related to the complaint handling system and lack of validation are repeat violations that were noted during the previous inspection of April 22, 1994. [21 CFR 820.20(b) (3)(i)]

In your written response, you declare that as part of your correction to this violation, GE Diasonics has been included in GEMS' internal audit program. In fact, you were part of GEMS internal audit program prior to our inspection, as evident by the Internal Audit Certification you provided for audit dates March 2 - 4, 1998. Furthermore, during the inspection, our investigator was informed that GEMS had conducted two audits prior to our inspection. One audit was conducted prior to GEMS' April 1998 acquisition of Diasonics, and a follow-up audit was conducted after the acquisition.

The other corrective actions you have taken and mentioned in your response in relation to this violation appear to be adequately addressed. We note that the GEMS Americas Quality Manual procedure you provided does not bear authorizing signatures or effective date. We will verify at a future inspection that this oversight has been corrected and that you have fully implemented the corrective actions which you have described.

2. You failed to ensure that the appropriate resources were allocated to the review and evaluation of complaints, field service reports, and trending of failure data. The investigator found that after May 6, 1998, Continuous Improvement Program meetings ceased. The intent of these meetings was to discuss significant issues concerning your firm's quality systems with key managers. After the cessation of these meetings, there was no formal evaluation of the statistical data by designated individuals to determine necessary corrective actions and to identify field service reports that should be handled through the complaint system. The fact that only two complaints were identified between May 6, 1998 and the inspection would seem to indicate lack of attention to complaint receipt, review, and evaluation. [21 CFR 820.20(b)(2), 820.20(b)(3)(ii)]

Your response is adequate. However, the procedure you provided, entitled Corrective and Preventive Action Procedure, which replaces the Continuous Improvement Procedure, has not been signed and dated for implementation. We will verify correction of this oversight as well as the adequacy of your corrective action during the next inspection.

3. You have failed to ensure that complaints are adequately investigated, that appropriate corrective action is taken, and that investigations and corrective actions are documented. During the inspection, at least twelve such incidents were noted. You have also failed on a number of occasions to ensure that complaints are closed in a timely manner. Nine such incidents were noted during the course of the inspection and included complaints which had been received between December 1996 and April 1998. [21 CFR 820.198]

Your response is adequate. However, the procedures you provided in your response as part of your corrective action, i.e., Global Handling of Product Complaints, Global Complaint Handling Procedure, and Device Reporting in GEMS Americas, have not been signed and dated for implementation. We will verify correction of this oversight and will evaluate the adequacy of your newly implemented complaint handling system during the next inspection.

4. You have not validated the de-ionized water systems and the water chilling loop from the ceramic cutting saws that are used in the manufacturing of the probes. Lack of validation of these systems was also noted during the previous inspection dated April 22, 1994. [21 CFR 820.75(a)]

Your response is inadequate in that you do not mention what you will do to ensure that the validation is done correctly. You indicate in your written response that [REDACTED] will complete validation of the DI Water System per specification. However, it is your responsibility to ensure that the validation is conducted correctly and adequately. We also note that none of the procedures which you provided as part of your corrective action, with the exception of the procedure entitled Phase Review Discipline, had been signed and dated for implementation. Your correction of this item will be evaluated during the next inspection.

5. You have failed to ensure that written procedures for validating the device design reflect the firm's current procedures. The investigator found that validation of the device design is currently done by [REDACTED] in [REDACTED] not by your Marketing group as indicated in the firm's written procedures. [21 CFR 820.30]

Your response is adequate. However, one of the procedures you provided, Engineering Procedures Manual, had not been signed and dated for implementation. We will verify during the next inspection that corrective measures have been fully applied.

The inspection also revealed that your firm is in violation of Section 519(f)(1) of the Act, in that on or about February 2, 1998, Disonics initiated a recall of the pediatric probes and failed to notify the U. S. Food and Drug Administration, as required by the Medical Device Corrections and Removals Regulation in section 21 CFR Part 806.

This letter is not intended to be an all-inclusive discussion of deficiencies at your facility or of the adequacy of your firm's response. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued to you, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. You are responsible for investigating and determining the causes of the violations.

You should take prompt action to fully correct these deviations. Failure to do so may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. We acknowledge that corrective measures are already being taken as you indicated in your October 14, 1998 response to the FDA483. We will verify full implementation of these measures during our next inspection of your firm.

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, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems as necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to the following:

Andrea P. Scott
Compliance Officer
U. S. Food & Drug Administration
96 North Third Street, Suite 325
San Jose, CA 95112

Please contact Sam Ali, Recall Coordinator at (510)337-6869 to inform him of the recall of the pediatric probes manufactured at your facility.

Sincerely,

Wayne L. Kaundell
Acting District Director

Patricia C. Ziobro
Director
San Francisco District