

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070

Telephone: (510) 337-6710

**WARNING LETTER****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our ref: 29-39814

April 22, 1997

Ashvin Desai  
President  
Ximed Medical Systems  
2195 Trade Zone Blvd.  
San Jose, CA 95131

Dear Mr. Desai:

An inspection of your firm located in San Jose, California was conducted between January 7 and January 27, 1997. Our investigators determined that your firm, Ximed Medical Systems, manufactures electrosurgical probes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection revealed that these devices are adulterated within the meaning of 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 Good Manufacturing Practice (GMP) Regulation for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The following items are representative of the violations observed during the inspection:

1. Failure to establish, implement, and control manufacturing specifications and processing procedures, as required by 21 CFR 820.100. The ethylene oxide processes which are used by your two contract facilities, [REDACTED] and [REDACTED], to sterilize the electrosurgical probes have not been validated. You have not demonstrated that the procedures and parameters for sterilization have been scientifically established. Additionally, you are unable to demonstrate that the parameters used are controlled to assure that the devices treated conform to approved specifications.

2. Failure to establish, implement, and control reprocessing procedures, as required by 21 CFR 820.115. There is no validated ethylene oxide cycle for reprocessing of the probes. To assemble a load sufficiently large to send to [REDACTED], your firm sometimes sends that company product which has previously been sterilized to add to a load of unsterilized product. The previously sterilized product is subjected again to ethylene oxide. You have not performed testing on these reesterilized products to assure that they meet original release criteria.
3. Failure to conduct all processing control operations in a manner designed to assure that the product conforms to all applicable specifications, as required by 21 CFR 820.100(b)(2). For example, on several occasions, the copy of the gas indicator strip from [REDACTED], which bore sterilization load information for one lot, had been modified and attached to the device history record for another lot. Further, your firm does not receive affirmation from [REDACTED] that sterilization loads have an acceptable biological indicator reading before releasing the probes to distribution, but relies upon a "nonresponse" from [REDACTED] as an indication that a load has undergone ethylene oxide treatment. A load had been processed on December 27, 1996 and released to shipping by Ximed. Three days later, [REDACTED] apprised Ximed that it was unable to locate the biological indicator for that load, and consequently was unable to provide assurance that the biological indicator for that load had undergone testing.
4. Failure to maintain an adequate device history record to assure that the products are manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, records are inadequate for accounting of probes sent to [REDACTED] for ethylene oxide sterilization. You are unable to determine the number of probes sent, the lot numbers sent, and are unable to correlate manufacturing lots to sterilization loads.
5. Failure to have adequate procedures for finished device inspection, as required by 21 CFR 820.160. For example, the probes are not subjected to testing after ethylene oxide processing.
6. Failure to identify, recommend, or provide solutions for quality assurance problems, as required by 21 CFR 820.20. For example, the written procedures regarding disposition and investigation of returned products are not being followed. The inspection revealed that returned products are often not ascribed a Returned Materials Authorization (RMA) number, the reasons for the returns are not investigated, and a response to the complainant is not generated.

We are aware that you have continued to try to use [REDACTED] as the contract sterilizer for your devices. We are aware that you have been advised by that firm that it does not possess the capability for properly sterilizing your devices, yet you have persisted in requesting that it do so.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

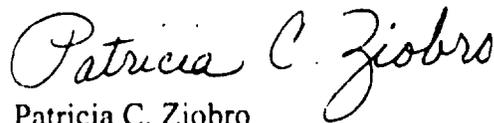
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonable related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export 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 the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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. Please include in your response an explanation of each step being taken to identify and correct any underlying systems problems which will assure that similar violations will not recur. If corrective action 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 Andrea P. Scott, Compliance Officer, Food and Drug Administration, 96 North Third St., Suite 325, San Jose, CA 95112.

Sincerely,



Patricia C. Ziobro  
District Director  
San Francisco District