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H.F.I-35



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Cincinnati District

Food & Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202-1097

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

February 25, 1997

WARNING LETTER  
CIN-WL-97-252

Cameron J. Fordyce, President  
Surgical Technology Laboratories, Inc.  
1588 E. 40th Street, Suite 1C  
Cleveland, Ohio 44103

Dear Mr. Fordyce:

During a recent inspection of your firm located at the above address by the Food and Drug Administration (FDA) our Investigator determined that your firm manufactures implantable Nasal, Chin, and Malar Prostheses. These implantable prostheses are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Inspection revealed that your 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 the Good Manufacturing Practice Regulations (GMP) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to validate the final cleaning procedure for the following devices: the Surgiform Nasal Prosthesis, the Surgiform Chin Prosthesis, and the Surgiform Malar Prosthesis. The instructions for the final cleaning of the devices before they are sterilized are contained in the product inserts for the devices.

Failure to validate the sterilization process for the following devices: the Surgiform Nasal Prosthesis, the Surgiform Chin Prosthesis, and the Surgiform Malar Prosthesis. The instructions for sterilizing the devices are contained in the product inserts for the devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA 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.

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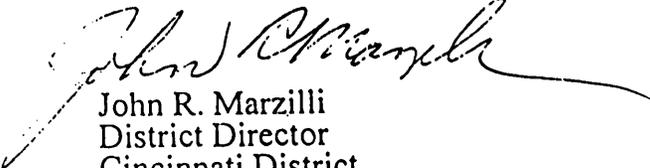
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until 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. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (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 prevent the recurrence of similar violations. 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 to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

  
John R. Marzilli  
District Director  
Cincinnati District