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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

707

Refer to: CFN 1122704

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 8, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jean E. Lang, President
Aerospace Machine
106 George Street, P.O. Box 520
Union Bridge, Maryland 21791

Dear Mr. Lang:

During a Food and Drug Administration (FDA) inspection of your firm located in Union Bridge, Maryland, conducted between October 14 and November 3, 1997, our investigator determined that your firm contract manufactures orthopedic implant devices for the specification developer [REDACTED]. The implant devices, known as the [REDACTED] are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (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, packing, storage or installation, are not in conformance with the Quality System Regulations (QS) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain, and document that in-process products meet requirements, as there was no documentation to show which in-process dimensions are to be measured for the components of the [REDACTED]
2. Failure to document that calibration has been performed on any measuring instruments since August 1994.

3. Failure to assure that incoming products meet specifications, as the Device Master Record (DMR) indicates specific ASTM grade materials are to be used, but there was no documentation showing that the materials used are, in fact, ASTM grade or equivalent.
4. Failure to maintain a complete Device History Record to show that devices are manufactured in accordance with the DMR.
5. Failure to assure that all equipment used in the manufacturing process meets specifications and has been adequately maintained.
6. Failure to document the disposition of the nonconforming product.
7. Failure to document that corrective and preventative actions are taken regarding nonconforming products.
8. Failure to document any internal audits of the Quality Assurance Program.
9. Failure to have a segregated area for defective or returned parts.

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 in the FDA-483 issued at the closeout of the inspection (enclosed) 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 pre-market submissions for devices to which the QS 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.

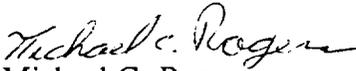
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We acknowledge your promise made at the close of the inspection to correct the deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter 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 necessary to 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 time, within which the corrections will be completed.

Your response should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200. Mr. Miller can be reached at 703-235-8440, extension 504.

Sincerely yours,


Michael C. Rogers
Acting Director, Baltimore District

Enclosure

cc:

