DEPARTMENT OF HEALTH & HUMAN SERVICES

g 40664
Public Health Service

Food and Drug Administrati
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-28

April 23, 2003

Loleta M. Magers, President
Alpha Industries, Inc.
701 N. Greenwood Avenue
Clearwater, Florida 33755

Dear Ms. Magers:

During an inspection of your establishment located in Clearwater, Florida on March 17- April 2, 2003, Investigator Sonia M. Monges determined that your establishment manufactures an umbilical cord clamp, tubing clamps, hemostats, and forceps. These products are used by physicians to perform manipulative diagnostic and surgical functions (e.g., dilating and grasping), where structural integrity is the chief criterion of device performance, and they 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 not in conformance with the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. Your devices are adulterated within the meaning Section 501(h) and misbranded within the meaning of Section 502(t)(2) of the Act.

Quality System Regulation

The investigator noted the following violations of the QS regulation:

1. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions (CAPA) and to document all activities as required by 21 CFR 820.100(a) and (b). The investigator determined that you do not have any procedures to implement CAPA and failed to document the corrective and preventive actions taken resulting from the receipt of a complaint involving an umbilical cord clamp (FDA 483, Item #1 & 3).

2. Your firm's executive management failed to establish, document and implement quality system procedures and instructions as required by 21 CFR 820.20(e). You informed the investigator during the inspection that you lacked the financial resources to comply with FDA regulations and should be exempt (FDA 483, Item #2).

3. Your firm failed to establish and maintain requirements, including quality requirements, that must be met by suppliers and contractors as required by 21 CFR 820.50(a). Your firm failed to establish purchasing controls as the specification developer of injection molding performed by contractors for disposable clamps, hemostats and forceps (FDA 483, Item #4).

4. Your firm failed to establish procedures to identify training needs and ensure that all personnel have sufficient training to adequately perform their assigned responsibilities as required by 21 CFR 820.25(b). Your firm admitted that personnel are trained on-the-job and that training is not documented (FDA 483, Item #6).

Medical Device Reporting (MDR)

The investigator noted that there was a failure to comply with a requirement prescribed under Section 519 of the Act as follows:

5. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17.

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. 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared or approved 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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District