



Food and Drug Administration
Denver District Office
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July 1, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert C. Padgett
President
The Aztech Group, Inc.
1401 Walnut Street, Suite 565
Boulder, CO 80302

Ref. # DEN-97-24

Dear Mr. Padgett:

During an inspection of The Aztech Group, Inc., Boulder, Colorado, conducted between May 6 and 21, 1997, by Investigators Nicholas R. Nance, Robert G. Antonsen and Joseph T. Goertz, it was determined that your firm imports and manufactures dental x-ray systems and accessories. These products are medical 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 adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to prepare and implement a quality assurance program that is appropriate to the specific device manufactured, as required by 21 CFR 820.5. For example, your firm has made changes to the [REDACTED] system [REDACTED] imported from [REDACTED]. No quality assurance program has been put into place and no documentation is maintained by your firm to demonstrate compliance with Good Manufacturing Practice Regulations.

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2. Failure to prepare a device master record which includes, or refers to the location of, device specifications, production process specifications, quality assurance procedures, and packaging and labeling specifications, as required by 21 CFR 820.181.
3. Failure to maintain device history records to demonstrate that the device is manufactured in accordance with the device master record, to include the dates of manufacture, the quantity released for distribution and any control number used, as required by 21 CFR 820.184. Modifications made to the Aztech 65 [REDACTED] timer by your firm constitute manufacture of a medical device. Your firm is not maintaining any of the above referenced documentation.
4. Failure to subject specification changes to controls as stringent as those applied to the original design specifications of the device. Such changes shall be approved and documented by a designated individual(s) and shall include the approval date and the date the change becomes effective, as required by 21 CFR 820.100(a)(2). For example, your firm is modifying the original design specifications of the Aztech 65 [REDACTED] timer and there is no documentation of formal, written approval of such design specification changes.
5. Failure to review, evaluate and maintain by a formally designated unit, records of complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device, as required by 21 CFR 820.198(a). For example, complaint reports do not always contain evidence to demonstrate that the report has been reviewed and evaluated, and do not always document the determination as to whether an investigation is necessary.
6. Failure to maintain written records of investigations into devices failing to meet performance specifications, including conclusions and follow-up, as required by 21 CFR 820.162. For example, there is not always evidence that failures of the [REDACTED] timers modified by your firm have been investigated. Further, there is not always evidence to demonstrate that failures of the Aztech 65 system have been forwarded to the original manufacturer for their investigation.

Our inspection also disclosed that your firm has failed to develop, maintain and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.

Finally, violations of Subchapter C of the Act - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) were observed. The Center for Devices and Radiological Health (CDRH) will review these deviations separately and any further correspondence in regards to those matters will issue from that office.

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Mr. Robert C. Padgett

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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 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.

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.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. 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 within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,


Gary C. Dean
District Director

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