



DEPARTMENT OF HEALTH AND HUMAN SERVICES

T20
Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

September 4, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Les W. Horn
Owner/President
Z Technologies, Inc.
2615 Woodacres Road
Atlanta, Georgia 30345

WARNING LETTER

Dear Mr. Horn:

An inspection of your firm was conducted on August 11 & 13, 1998, by Investigator Fulton A. Varner. Our investigator found that you are manufacturing transcutaneous electrical nerve stimulators (TENS). These stimulators are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented several significant deviations from the Quality System Regulation as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to implement and maintain a device master record for your TENS device. The device master record should include device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications. You have failed to establish and maintain procedures for acceptance of incoming products and components. No specifications had been established for any of the approximately [REDACTED] components utilized in the assembly of your device. No documentation existed to indicate that any of these components had been subjected to an incoming inspection to assess its suitability for use in your device.

You have failed to establish and maintain procedures for finished device acceptance to ensure that each device meets acceptance criteria. No formal documented finished product specifications had been established for final product testing prior to release for distribution. No acceptance criteria has been established. The test methods to be utilized for final product release had not been formally established and approved.

You have failed to maintain device history records for each of the units manufactured at your facility. You have failed to establish and maintain procedures to ensure that device history records for each unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and established product specifications. No such records were available for any of the units manufactured and distributed for commercial and demonstration purposes.

You have failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. These procedures should also include procedures to address the handling of complaints under the Medical Device Reporting requirements delineated in 21 CFR, Part 803. Other critical procedures which have not been established included the procedures for quality audits. These audits are required to assure that your quality system is in compliance with the established quality system requirements and to determine the effectiveness of your quality system.

You have failed to ensure that all inspection, measuring, and test equipment is suitable for its intended purposes and is capable of producing valid results. You had not established and maintained procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained. No calibration data was available for any of the inspectional instruments utilized to verify the operational characteristics of your devices, including finished product release testing.

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. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 are symptomatic of serious underlying problems in your firm's 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. Also, no request for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

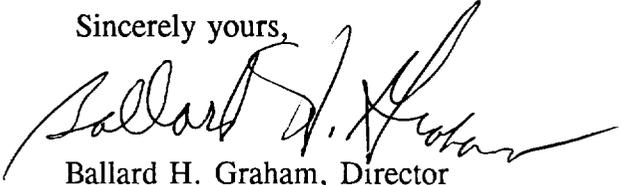
You should take prompt action to correct these deviations. We acknowledge that some corrective measures were undertaken during the course of the inspection. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) 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 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.

We are in receipt of the August 27 response from your firm to the FDA 483. That response is currently under review and our comments to that response will be forwarded in another letter. You may reference your initial response in your Warning Letter response, if you feel that it adequately addresses any of the issues raised in this letter. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ballard H. Graham, Director
Atlanta District