



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

n:2234n

DB 12/14/98

Certified/Return Receipt Requested

December 11, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Nelson Shirley, President
Control System International, Inc.
8040 Neuman Road
Lenexa, KS 66214

KAN #99-007

Dear Mr. Shirley:

A recent inspection of your manufacturing operation located at 1319 Central, Kansas City, Kansas, determined you are manufacturing a shortwave diathermy device. This is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

This inspection was conducted on November 4 through 17, 1998, by Food and Drug Administration Investigators from this office. Your shortwave diathermy device is 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 current Quality System Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, to include, but not be limited to, the following:

failure to establish and maintain a quality system that is appropriate for the shortwave diathermy device [21 CFR 820.5];

failure to appoint a member of management with executive responsibilities to implement the quality system [21 CFR 820.20(a)];

failure to establish procedures for internal quality audits of the quality system [21 CFR 820.22];

failure to establish and maintain procedures to ensure that documents used during production are the most current and approved documents [21 CFR 820.40];

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failure to establish procedures to ensure that all purchased device components conform to specified requirements [21 CFR 820.50];

failure to document inspections on incoming device components [21 CFR 820.80(b)];

failure to establish and maintain procedures for implementing corrective and preventive actions [21 CFR 820.100];

failure to establish and maintain procedures for statistical sampling and inspection of incoming device components [21 CFR 820.250(b)].

This letter is not intended to be an all-inclusive list of deficiencies at your Kansas City, Kansas, facility. At the conclusion of the inspection Form FDA 483 was issued to Mr. Cary Gray, Engineer. A copy is enclosed for your information. 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 Form FDA 483 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.

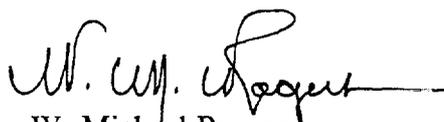
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

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Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", with a horizontal line extending to the right.

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483