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OCT 16 2001

## WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ed Parker  
President  
E.M. Parker  
400 Research Drive  
Wilmington, Massachusetts 01887-0540

Dear Mr. Parker:

On May 29, 2001, a field test was performed on a diagnostic X-ray system your firm installed at [REDACTED], [REDACTED], New Hampshire on February 16, 2001 (FDA2579 # [REDACTED]). We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), Subchapter J).

Analysis of the data obtained from the field test shows the Sedecal generator and the control panel fail to comply with the following requirements of the Federal performance standard for diagnostic X-ray systems:

1. The control panel was not certified (21 CFR 1010.2(a) & (b)).
2. The control panel did not contain the required identification (21 CFR 1010.3).
3. The High Voltage Generator was not certified (21 CFR 1010.2(a) & (b)).
4. The High Voltage Generator did not contain the required identification (21 CFR 1010.3)

The report of assembly (FDA 2579) filed by an assembler is construed as the assembler's certification and identification under 21 CFR 1010.2 and 1010.3 of 21 CFR, Subchapter J, Radiological Health (21 CFR 1020.30(d)(1)). The Food and Drug Administration (FDA) 2579 you filed for this system certified "I affirm that all certified components assembled or installed by me, for which this report is being made ... were of the type

Page 2 - Mr. Parker

required by the diagnostic x-ray performance standard (21 CFR Part 1020) ... ". This is a false assembler certification for this installation.

You are advised that it is a prohibited act under the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968), to introduce, or deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard pursuant to section 534 (U.S.C. 3600o(a)(1)).

Within 15 working days of the receipt of this letter, please furnish us with:

1. a list of all systems you have installed that contain components that are not certified and for which the components do require certification.
2. copies of your correspondence to the manufacturer of the component(s) notifying them of the uncertified component(s).
3. a corrective action plan (21 CFR 1004) to:
  - a. notify the system owner(s) of the uncertified components.
  - b. correct the FDA 2579(s).
  - c. replace the uncertified components with certified components.
4. steps that will be taken to prevent the reoccurrence of installing uncertified components.

If your response is not received within 15 working days, the FDA may consider you to be in violation of section 538(a)(2) of the Act for failure to submit required reports. FDA considers failing to respond to this letter, failing to correct these products in a timely manner, or submitting false statements to the FDA to be serious violations of U.S. law and can result in regulatory action being initiated by the FDA without further notice. These actions may include seizure and/or injunction and/or imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are

Page 3 - Mr. Parker

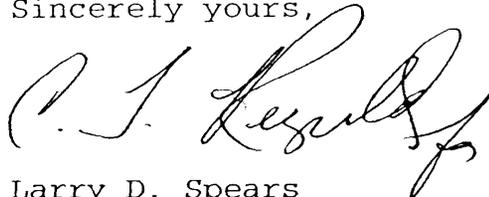
subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

If you require additional time to prepare your refutation, notification, CAP, or evidence to support an exemption request, you must submit a written request to this office which outlines the reasons for any delays and a reasonable target date for submission of your response. This request must be submitted within 15 working days of the receipt of this letter. Please direct your response to Heyward Rourk, Diagnostic Devices Branch, Office of Compliance (HFZ-322), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, New England District Office (HFR-NE200), One Montvale Avenue, 4<sup>th</sup> Floor, Stoneham, Massachusetts 02180.

If you have specific questions about the content of this letter, please feel free to contact Mr. Heyward Rourk at (301) 594-4591 extension 157.

Sincerely yours,



Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health