



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M 24201

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED RAK

April 9, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-24

John Welch, Jr.
Chief Executive Officer
General Electric Company
3135 Easton Turnpike
Fairfield, Connecticut 06431

Dear Mr. Welch:

We are writing to you because on March 8-12, 1999, investigators from the Food and Drug Administration (FDA) collected information from your Marquette Medical Systems, Milwaukee, WI, facility that revealed a serious regulatory problem involving the software for your Solar Model 7000/8000 Patient Monitors.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Patient Monitors and their associated software are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of the medical devices are not

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in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations (CFR), Part 820.

Our inspection found your products are in violation of the law because of:

1. Failure to establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality [21 CFR 820.20] in that there is no provision in your firm's Quality Manual for the coordination of responsibilities and activities concerning the corrective and preventive action system (FDA-483 item #7).
2. Failure to establish and maintain procedures for validating the device design, and failure to assure that devices conform to defined user needs and intended uses, including testing under actual or simulated use conditions, as required by 21 CFR 820.30(g). For example:
 - a. The decision to not perform a hazard assessment for the software version change from 5C to 5D was not justified (FDA-483 item #1).
 - b. Proper installation and verification of functionality was not performed for software version 5D loaded into a Model 7000/8000 already possessing versions 5A, 5B, or 5C (FDA-483 item #3).
 - c. The version 5C to 5D software change was not properly validated prior to the original release of 5D (FDA-483 item #4).
 - d. Validation Procedure MDM 5002, Rev F, MEF 28's and MEF 66's for XO1,02, and X03 "cuts" do not include proper instructions for thorough validation of software changes. After version 5D was changed, version 5D was not loaded into the Model 7000/8000 unit to assure that the essential functions would properly operate (FDA-483 item #5).
3. Failure to establish and maintain procedures for verifying the device design so that the design output conforms to the design input [21 CFR 820.30(f)]

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in that proper execution of version 5D software was not tested or verified for all critical modes in a Model 7000/8000 unit prior to release of version 5D (FDA-483 item #2).

4. Failure to establish and maintain procedures for final device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria in that the Finished Device Test TP900691-0XX, Rev H does not verify essential functions of the Model 7000/8000 Solar ECG Monitors [21 CFR 820.80(d), FDA-483 item #6].
5. Failure to establish and maintain procedures for implementing corrective and preventive action [CAPA, 21 CFR 820.100(a)] in that your firm's CAPA procedures were not followed in investigating complaint #M6142(FDA-483 item #8).
6. Complaints do not always include all of the information required to be gathered in accordance with 21 CFR 820.198, e.g. complaint #M6142 (FDA-483 item #10).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at General Electric Company, it is ultimately your responsibility to ensure that devices manufactured at your Marquette Medical Systems facility in Milwaukee, WI, are in compliance with each requirement of the Act and regulations.

The specific violations noted in this letter and in the FDA-483 issued at the close-out 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 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

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against further marketing of the 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. Additionally, no pending applications for pre-market approval (PMA's) or export approval requests will be approved and no pre-market notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

We received your March 19, 1999, letter responding to the FDA-483 issued on March 12, 1999. Additionally, we met with representatives from GE, Marquette Medical Systems, and your legal counsel on April 5, 1999, to discuss the actions that have been taken to address the concerns referenced in the FDA-483. Our review of the March 19 letter and documents provided to us at the meeting finds that the corrective actions that you are taking are appropriate.

Your responses to the specific items will be evaluated by inspection to verify that the procedures, documentation, and training that you have proposed have been effectively implemented. We acknowledge that your firm has set  as the date when implementation of, and training on, the new procedures will be completed.

Any further response you may have should be directed to the attention of Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

We would also advise you that the field correction of the Solar 7000/8000 Patient Monitors with the software problems has been classified as a Class I Recall. This was discussed further in a Recall notification letter sent to Mr. Frederick A. Robertson, President, Marquette Electronics, Inc., on April 7, 1999.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical

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devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,



James A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 3/12/99

xc: Frederick A. Robertson
President and CEO
GE Marquette Medical Systems
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Milwaukee, WI 53223

Jack O'Malley
Vice President, General Counsel, and
Secretary
GE Marquette Medical Systems, Inc.
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