



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 15, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-34

Richard O. Martin, President
Medtronic Physio-Control
11811 Willows Road
Redmond, Washington 98073-9706

WARNING LETTER

Dear Mr. Martin:

We are writing to you because during an inspection from October 21, 1999, to February 11, 2000, the Food and Drug Administration (FDA) became aware of information that revealed a serious regulatory problem involving the Lifepak 500 Automated External Defibrillator which is manufactured and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), your firm is required to submit a written report to FDA within ten working days of initiating either a product correction or removal that is intended to: (1) reduce a risk to the public health; or (2) remedy a violation of the Act which may present a risk to health. These reports will help FDA protect the public health by improving the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

Our records indicate your firm has initiated a correction, as defined by Title 21 of the Code of Federal Regulations (21 CFR) Part 806, and has not submitted the required report to your local FDA District Office at:

U.S. Food and Drug Administration
Recall Coordinator
22201 23rd Drive SE
Bothell, WA 98021-4421

The correction involved a June 5, 1998, action for field units as a result of failure of the R-4 resistor. The resistor failed as a result of damage from an adjacent assembly. Because you have not submitted a report of corrections, your product is in violation of the law. In legal terms, the product is misbranded under section 502(t)(2) of the Act for failure to make a report as required by Section 519 of the Act.

Richard O. Martin, President
Medtronic Physio-Control
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The above stated inspection also revealed that this 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 Quality System Regulation (QSR) for medical devices as specified in 21CFR 820, as follows:

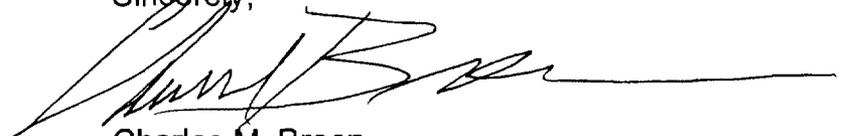
The corrective and preventive action with regard to failure of the R-4 resistor was ineffective in that field failures of the resistor have continued despite the corrective action issue date of June 5, 1998. The failures have occurred in units that had not been checked and also in units that had been serviced.

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 the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please notify us in writing within fifteen (15) working days from the date you received this letter, what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Thomas S. Piekarski, Compliance Officer, at the above address.

Finally, you should understand there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of reporting corrections and removals for your device 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 devices by contacting our Division of Small Manufacturers Assistance at 800-638-2041 or through the Internet at www.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal line extending to the right.

Charles M. Breen
District Director