DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401-1999
Telephone: (612) 334-4100
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November 01, 2007

William A. Hawkins
President and Chief Executive Officer
Medtronic, Inc.
710 Medtronic Parkway
Mailstop LC400
Minneapolis, Minnesota 55432-5604

RE: Recall Numbers Z-0067-2008 thru Z-0070-2008

Dear Mr. Hawkins:

You should be in receipt of a letter from Daniel G. Schultz, M.D., Director, FDA Center for Devices and Radiological Health, dated October 16, 2007, notifying you of the Class I recall classification on Medtronic Sprint Fidelis Leads models 6930, 6931, 6948 and 6949, due to potential lead fractures which have a reasonable probability to cause serious adverse health consequences, including death.

Our evaluation indicates that this recall should be conducted to the physician level and that Level A effectiveness checks should be conducted by your firm. Level A effectiveness checks are to be conducted at 100% of your consignees to verity that all consignees have received notification about the recall and have taken appropriate action.

In addition to your recall efforts, it is equally important to assure that all returned or undistributed merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our experience in similar situations has shown that, the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

We request that you advise us within ten (10) days of the steps you have taken or will take to ensure the recalled product is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods and your undistributed stock.

In addition, we request you submit to our Minneapolis District Office a recall status report at monthly intervals, beginning the month of December, until completion of the recall. If you have completed your recall actions at this time, you will only need to send one summary report. The recall status report should contain the following information:

1. Number of consignees notified of the recall, and date and method of notification.
2. The number of consignees responding to the recall communication.
3. Number of consignees that did not respond.
4. The number of consigned devices retrieved from hospitals or other consignee inventories, and the quantity of product accounted for.
5. Date, number, type (telephone, visit, etc.) and results of effectiveness checks that were made.

6. The estimated time frame for completion of the recall, or when the recall was completed.
7. Amount of the product on hand at your firm when the recall began, and the disposition of this product.
8. Corrective actions taken to prevent recurrence of the situation.
9. Number and summary of complaints received about lead fractures.

Address these periodic recall status reports to Kristy Zuroski, Recall & Emergency Coordinator at the Minneapolis District Office. Information indicated as needed in items 7-9 is for closing the recall, and need only be supplied in your final report.

Our judgment, regarding the effectiveness of the recall, will largely be based upon your implementation of the guidelines addressed in the FDA "Enforcement Policy" 21 CFR part 7, and "Methods for Conducting Recall Effectiveness Checks". Please be advised that failure to conduct an effective recall could result in seizure of the violative product in commerce, or other legal sanctions under the Food, Drug & Cosmetic Act.

Your response to this letter should be addressed to W. Charles Becoat, District Director.

Your cooperation in this matter is obviously important for the protection of the general public.

Sincerely,

H. Tom Warwick for:
W. Charles Becoat
Director
Minneapolis District

Enclosure

cc: Michael G. Holgers
Director of CRDM Compliance
Medtronic Cardiac Rhythm Disease Management
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432-3576