DEPARTMENT OF HEALTH AND HUMAN SERVICES

5/1/04

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

Telephone: 425-486-8788
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July 14, 2003

VIA CERTIFIED MAIL

In reply refer to Warning Letter SEA 03-22

Joachim Langer
Vice President and General Manager
Biotronik, Inc.
6024 Jean Road
Lake Oswego, Oregon 97035

WARNING LETTER

Dear Mr. Langer:

We are writing to you because during an inspection from April 8 through April 17, 2003, the Food and Drug Administration (FDA) became aware of information that revealed a serious regulatory problem involving the Belos VR and Belos VR-T. As the US Agent and initial distributor of these products, your firm is responsible for these violations.

Your Belos VR and Belos VR-T Implantable Cardioverter Defibrillators (ICDs) are misbranded within the meaning of Section 502(t)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) in that a report of correction or removal was not submitted to FDA as required by Section 519(f)(1) of the Act. The Correction and Removal Regulation (21 CFR 806), promulgated under Section 519(f)(1), requires manufacturers and importers to promptly report to FDA, within 10 working days, any correction or removal of a device to reduce a risk to health.

Our Inspection revealed that on or about March 21, 2003, your firm notified all physicians implanting your Belos VR and Belos VR-T ICDs to immediately schedule a follow-up visit with each patient and:

a) "...examine the charge times in the shock table to assess whether any charge time was 16 seconds. If such an abnormal charging time is observed, the device should be replaced immediately because the full programmed energy may not be delivered..."

b) "...In those devices that do not exhibit a 16-second charge time, perform six (6) manual capacitor reformations. Please wait at least 1 minute between two consecutive manual reformations. After the 6 reformations, please wait 1 minute and then examine the charge times. Again, if a charge time of 16 seconds is

observed at least once, the full programmed energy may not be delivered and the device should be scheduled for immediate replacement..."

c) "...For devices without any 16-second charge times shown in the shock history table (after 6 capacitor reformations), we recommend programming the automatic capacitor reformations to every 3 months. Patients should then be followed normally (quarterly follow-ups)..."

As FDA informed you by letter dated May 14, 2003, FDA has classified your March 2003 notification to physicians implanting your Belos VR and Belos VR-T ICDs as a Class II recall. A Class II designation indicates that exposure to the violative product may cause temporary adverse health consequences. See 21 CFR 7.3(m). FDA regulations require manufacturers and importers to promptly report to FDA any correction or removal of a device if the correction or removal was initiated to reduce a risk to health. See 21 CFR 806.10 (a)(1). Because your firm's action described above meets the definition of a "removal" in 21 CFR 806.2(i) and because FDA has found that the removal was initiated to reduce a risk to health, your failure to report the product removal until the issue was raised by our investigator violated 21 CFR 806.10(a)(1).

You should take prompt action to correct this violation and prevent its reoccurrence in the future. Failure to promptly correct these violations may result in FDA initiating regulatory action without further notice. 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.

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 Bruce W. Williamson, Compliance Officer, at the above address.

Sincerely,

Charles M. Breen
District Director