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March 17, 2003

BY ELECTRONIC FILING

Federal Communications Commission
Office of Engineering and Technology
Laboratory Division
Equipment Authorization Branch
7435 Oakland Mills Road
Columbia, MD 21046

**Re: Biotronik, Inc. (Grantee Code: PG6)
Application for Equipment Authorization (Form 731)
For the Belos VR-T and Belos DR-T Implantable
Cardioverter Defibrillators and the Cardiac Airbag-T
Medical Implant Devices**

Dear Sir or Madam:

Submitted herewith on behalf of Biotronik, Inc. ("Biotronik"), is an application on FCC Form 731 for a new equipment authorization for the following medical implant devices: (1) the Belos VR-T implantable cardioverter defibrillator ("ICD"); (2) the Belos DR-T ICD; and (3) the Cardiac Airbag-T. These devices, all having identical RF transmission circuits, will operate pursuant to the Medical Implant Communications ("MICS") service rules (Part 95, Subpart I) and will transmit operational, diagnostic, and therapeutic information associated with their use by cardiac patients to healthcare professionals via the cellular telephone network.

The devices subject to the instant application offer a single mode of transmission for which authorization is sought. The devices transmit when certain cardiac and

technical events are detected by the implant device itself, known as "event messaging."¹ The Commission has determined that this mode of transmission is exempt from the frequency monitoring requirements contained in Section 90.628(a) of the MICS rules.²

In addition, the devices subject to this application have the capability of offering regularly scheduled transmissions, which are preprogrammed by the implant patient's physician. On February 25, 2003, the Commission issued an order finding that such preprogrammed, regularly scheduled transmissions on a single channel without prior frequency monitoring do not comport with the MICS rules.³ The instant application, therefore, does not seek authorization to use the scheduled transmission features of the Belos VR-T, Belos DR-T, and Cardiac Airbag-T medical implant devices. This application, however, is being submitted without prejudice to any action Biotronik may take with respect to the Commission's February 25, 2003 decision, or with respect to obtaining authorization for preprogrammed, regularly scheduled transmissions by the devices that are subject to this application or by any future Biotronik devices.

Please direct questions concerning this application to Mr. James Horton, Senior Program Manager for Biotronik, by e-mail at hortonj@biotronikusa.com or by phone at (503) 387-2640.

Respectfully submitted,

A handwritten signature in black ink that reads "Henry Goldberg". The signature is written in a cursive, flowing style.

Henry Goldberg
Attorney for Biotronik, Inc.

Attachments

cc: Mr. Julius Knapp (w/o attachments)
Mr. Bruce Romano (w/o attachments)

¹ See Section 2.8.2.4 of Technical Manual for Belos Family of Implantable Cardioverter Defibrillators and Section 2.6.1.4 of the Technical Manual for the Cardiac Airbag-T, submitted herewith.

² See Letter Order from Bruce A. Franca, Deputy Chief, Office of Engineering and Technology, FCC ID. No. PG6BA0T (Mar. 8, 2002) at 2 ("OET Letter Order"), *aff'd*, *In re Biotronik, Inc., Equipment Authorization for the Medical Implant Communications Service*, Memorandum Opinion and Order, FCC Identifier No. PG6BA0T, FCC 03-32, ¶11 (rel. Feb. 25, 2003).

³ See MO&O at ¶15.

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Mr. James Burtie (w/o attachments)