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February 11, 2003

**REDACTED VERSION –
FOR PUBLIC INSPECTION**

BY HAND

Mr. James Burtle
Chief, Experimental Licensing Branch
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, S.W.
Washington, DC 20554

Re: **Biotronik, Inc.**
Experimental Radio Station License
File No. 0223-EX-PL-2002
Call Sign WD2XAA

Dear Mr. Burtle:

On behalf of Biotronik, Inc. ("Biotronik"), this responds to your letter dated January 21, 2003, requesting further information concerning Biotronik's ongoing clinical study of the Belos DR-T medical implant device conducted pursuant to experimental authority.¹ Contrary to the charges leveled in Medtronic's Petition,² Biotronik is conducting a *bona fide* experiment with the Belos DR-T and receives no compensation for the equipment authorized by the Commission to be used in those experiments.

Attached to this letter are copies of sample Physician and Research Agreements that investigators participating in clinical trials of the Belos DR-T enter into with

¹ See Experimental Radio Station Construction Permit and License, Biotronik, Inc., Call Sign WD2XAA, File No. 0223-EX-PL-2002 (granted Oct. 21, 2002).

² See Petition for Reconsideration filed by Medtronic, Inc., File No. 0223-EX-PL-2002 (Jan. 2, 2002).

Biotronik.³ Also attached for your information is a copy of Biotronik's most recent response to the unfounded charges Medtronic has made in its recent filings with the Commission.

As explained in the attached Biotronik response, the Belos DR-T, which is an enhanced version of Biotronik's Belos DR medical implant device, consists of an implantable cardioverter defibrillator (ICD) containing a T chip, which may be turned off or on and also includes external home monitoring equipment. Neither the T chip nor the home monitoring equipment is integrated with or essential to the functioning of the medical implant device itself, but these components do require Commission authorization due their transmission capabilities.

Biotronik applied for experimental authority so that it could conduct clinical trials on the transmission features of the T chip and home monitoring equipment. and does not charge patients participating in it clinical trials for these components. However, the implants used with the Belos DR-T, without the T-chips and home monitoring equipment, are identical to ordinary Belos DR devices, which do not offer transmitting capabilities and which Biotronik is permitted to market and sell without having to seek Commission approval. For that reason, Biotronik does receive compensation for the implant devices used with the Belos DR-T.

An ordinary Belos DR implant device, without transmission capabilities, has a list price of []. On average, Biotronik charges participating institutions approximately [] of that price for each implant device used in the clinical study, although this price will vary from institution to institution participating in the clinical study. At this time, Biotronik does not know the market value of the T chip technology and the home monitoring equipment and services used with the Belos DR-T, which is one reason for the clinical trial and the experimental authorization. Consequently, Biotronik has not determined a price for these components and is not charging for them in the clinical trial. In summary:

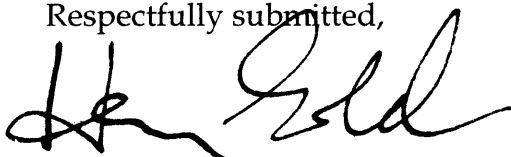
MSRP of Belos DR (without T-Chip) = []
MSRP of Belos DR-T = To be determined
Amount charged for T-Chip capability and
associated home monitoring equipment and services = \$0.00

³ Biotronik requests confidential treatment of these agreements and of the financial data disclosed in this letter. See attached Request for Confidential Treatment.

Mr. J. Burtle
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Please direct any questions concerning this matter to the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "H. Goldberg", written over the typed name.

Henry Goldberg
Joseph A. Godles
Attorneys for Biotronik, Inc.

Attachments

cc: Mr. Bruce Romano, Esq.
Mr. David E. Hilliard, Counsel to Medtronic, Inc. (redacted version)