

LAW OFFICES
GOLDBERG, GODLES, WIENER & WRIGHT
1229 NINETEENTH STREET, N.W.
WASHINGTON, D.C. 20036-2413

HENRY GOLDBERG
JOSEPH A. GODLES
JONATHAN L. WIENER
MICHAEL A. McCOIN
BRITA D. STRANDBERG

HENRIETTA WRIGHT
THOMAS G. GHERARDI, P.C.
COUNSEL

(202) 429-4900
TELECOPIER:
(202) 429-4912
e-mail:
general@g2w2.com
website: www.g2w2.com

October 16th, 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 Lexos T Implantable Cardioverter Defibrillator
Medical Implant Device**

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 Lexos T, Biotronik's next generation implantable cardioverter defibrillator ("ICD"). This medical implant device 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 its use by cardiac patients to healthcare professionals via the cellular telephone network.

The Lexos T offers a single mode of transmission for which authorization is sought. The device transmits when certain cardiac and technical events are detected by the implant device itself, known as "event messaging." The Commission has

Oct. 16th, 2003

Page 2

determined that this mode of transmission is exempt from the frequency monitoring requirements contained in Section 95.628(a) of the MICS rules.¹

In addition, the Lexos T has the capability of offering regularly scheduled transmissions, which are preprogrammed by the implant patient's physician. On March 27, 2003, Biotronik sought a waiver of the MICS rules to permit its cardiac implant devices to use preprogrammed regularly scheduled transmissions on a single channel without prior frequency monitoring. As Biotronik's waiver request remains pending, this application does not seek authorization to use the scheduled transmission mode of the Lexos T device. This application, however, is being submitted without prejudice to Biotronik's pending waiver request, or with respect to obtaining authorization for the Lexos T's preprogrammed, regularly scheduled transmissions or for 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)
Mr. James Burtle (w/o attachments)

¹ 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, 18 FCC Rcd 3027, ¶11 (2003).