

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of)
)
Amendment of Parts 2 and 95 of the)
Commissions' Rules to Establish The) RM No. 11271
Medical Data Service at 401-402 and)
405-406 MHz)

REPLY COMMENTS OF BIOTRONIK, INC.

Biotronik, Inc. ("Biotronik"), by its attorneys, hereby submits this reply to the initial comments filed in support of Medtronic's Petition for Rulemaking ("Petition") in the above-captioned proceeding. None of the parties supporting the Petition have demonstrated that the proposed rule changes – the creation of a new Medical Data Service ("MEDS") and the segregation of Medical Implant Communications Service ("MICS") transmissions - actually are needed or make the best use of the spectrum. Biotronik urges the FCC instead to initiate its own rulemaking proceeding, as indicated in the approval of Biotronik's waiver request,¹ and change the MICS rules to accommodate a wider range of devices, including those that do not use listen-before-transmit technology.

DISCUSSION

The record does not support the Petition's claims that it is necessary to allocate additional spectrum and create MEDS for a new class of wireless medical implants. First, none of the commenters shows that there is congestion on the present MICS frequencies or that other technologies cannot be used for communications between

¹ See *In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 19 FCC Rcd 4208, 4214 (2004) ("Biotronik Waiver").

external devices. There is, moreover, no showing of any need to change the allowed use of the MICS band from “life sustaining” to “time sensitive, life critical” data.

Second, the record does not support the need to require medical implants that do not employ listen-before-transmit technology to move to other frequencies and be restricted in their power and duty cycles. The few parties supporting the Petition do not demonstrate that devices that do not employ listen-before-transmit technology have or will cause interference to other MICS devices.

While Medtronic claims that its proposed rule changes will promote the “expanded use” of MICS,² the opposite is true. The segregation of MICS devices proposed by Medtronic is not only unnecessary, but would prevent medically useful devices from being made available to the public.

Further, Biotronik notes that, notwithstanding the comments of Zarlink Semiconductor (“Zarlink”),³ even today not all MICS medical devices can be designed to be compliant with the MICS listen-before-transmit requirements. It is difficult to design implantable medical devices employing bidirectional communications; there are many more factors involved in the design of such devices than the availability of transceiver chips.

In sum, Biotronik opposes the creation of MEDS and the proposed segregation of certain MICS devices into the new spectrum. Biotronik believes that the MICS rules instead should be changed to allow flexibility in the MICS spectrum and to accommodate a wider range of devices, including devices that do not meet the present listen-before-transmit requirements. This would more immediately serve the needs of patients by allowing medically effective devices to operate within MICS without waivers. Moreover, FCC should ensure that its MICS rules are consistent with those

² *In the Matter of Amendment of Parts 2 and 95 of the Commissions’ Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Comments of Medtronic at 2.

³ *In the Matter of Amendment of Parts 2 and 95 of the Commissions’ Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Comments of Zarlink Semiconductor at 3.

abroad so that medical implant manufacturers will have the economies of scale necessary to participate in a global marketplace.

Respectfully submitted,

BIOTRONIK, INC.

A handwritten signature in black ink that reads "Henry Goldberg". The signature is written in a cursive style with a large, prominent "H" and "G".

By: _____

Henry Goldberg

Laura Stefani

GOLDBERG, GODLES, WIENER & WRIGHT

1229 Nineteenth Street, N.W.

Washington, D.C. 20036

(202) 429-4900

Its Attorneys

October 11, 2005

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Reply Comments of Biotronik, Inc., was sent by first-class mail, postage prepaid, this 11th day of October, 2005, to the following:

Robert L. Pettit
David E. Hilliard
John W. Kuzin
Wiley, Rein & Fielding, L.L.P.
1776 K St., NW
Washington, DC 20006
Counsel for Medtronic

Bruce Romano
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

_____/s/_____
Candace Gentry