Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

ORIGINAL

In the Matter of	)	
	)	
Biotronik, Inc.	)	
	)	File No. 0223-EX-PL-2002
Experimental Radio Station License (Call Sign WD2XAA)	)	
	)	

RESPONSE TO MEDTRONIC REPLY

Biotronik, Inc. ("Biotronik"), by its attorneys, submits this Response to the Reply of Medtronic regarding Biotronik's above-captioned experimental authorization.[1] In its Reply, Medtronic not only attempts to perpetuate misconceptions about Biotronik's duly authorized equipment, but also distorts statements Biotronik made in its Opposition to Medtronic's Petition for Reconsideration.[2] Biotronik hereby sets the record straight.

Contrary to Medtronic's contentions, the Belos VR-T and Belos DR-T are the subject of ongoing, *bona fide* experimentation authorized by the Commission.[3] Biotronik is not selling or marketing these devices in the United States and therefore the license conditions Medtronic proposes are unnecessary. In addition, the alleged "automatic transmission feature"[4] of Biotronik's medical implant devices are in reality scheduled transmissions that must be activated and programmed by the patient's attending

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[1] *See* Reply of Medtronic, File No. 0223-EX-PL-2002 (Jan. 22, 2003) ("Medtronic Reply").
[2] *See* Opposition to Petition for Reconsideration, filed by Biotronik, Inc., File No. 0223-EX-PL-2002 (Jan. 15, 2003) ("Biotronik Opposition").
[3] *See* Experimental Radio Station Construction Permit and License, Biotronik, Inc., Call Sign WD2XAA, File No. 0223-EX-PL-2002 (granted Oct. 21, 2002) (Belos DR-T), and Experimental Radio Station Construction Permit and License, Biotronik, Inc., Call Sign WC2XWI, File No. 0062-EX-PL-2002 (granted Apr. 12, 2002) (Belos VR-T).
[4] Medtronic Reply at 2.

physician. These transmissions, therefore, qualify as medical implant events under the Commission's Medical Implant Communications (MICS) rules.[5] For these reasons, Biotronik respectfully asks the Commission to dismiss or deny Medtronic's Petition for Reconsideration.

I. BIOTRONIK IS CONDUCTING VALID EXPERIMENTS.

Medtronic contends that Biotronik is using the Commission's experimental licensing rules as "a shield for the marketing and sale of the Belos VR-T and DR-T devices."[6] Medtronic's accusation is untrue. As explained below, Biotronik is not marketing the Belos VR-T or the Belos DR-T in the United States. The Belos VR-T and the Belos DR-T, moreover, are the subject of genuine experimentation to test the wireless remote-monitoring components used with the devices. Such experiments are vital to evaluating the effectiveness of this technology in clinical settings.

The Belos VR-T and the Belos DR-T devices are enhanced versions of Biotronik's Belos VR and Belos DR devices, respectively. The more advanced Belos VR-T and Belos DR-T, unlike their Belos VR and Belos DR counterparts, include a "T chip" in the implant itself and include external home monitoring equipment. Neither of these components is integrated with or essential to the usual functioning of the medical implant device itself. As an enhanced feature, the home monitoring equipment receives therapy-relevant information from the T chip in the patient's implant and transmits that data to the patient's physician. The less sophisticated Belos VR and Belos DR, which do not contain a T chip, offer no such transmitting or remote-monitoring capabilities and thus do not require equipment or radio transmission authority under the Commission's rules.

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[5] *See* 47 C.F.R. § 95.628(b); *see also* 47 C.F.R. Pt. 95, Subpt. E, App. 1. (defining "medical implant event"). As shown below, when Medtronic proposed the definition of a medical implant event, it offered an interpretation that encompasses Biotronik's scheduled tranmissions.

[6] Medtronic Reply at 3.

Medtronic is wrong when it says that Biotronik is "dissecting a single integrated device . . . into two parts": one requiring Commission authority and one not.[7] It is the Commission's rules that "dissect" the device, since only the transmission function and equipment must be authorized under Part 15. The Belos VR and Belos DR do not have this function and are marketed and used without FCC authorization.

Biotronik applied for experimental authority so that it could test the T chip and home monitoring equipment used with the Belos VR-T and Belos DR-T devices. That is precisely the kind of testing for which experimental licenses are available – Biotronik seeks to advance the state of the art by developing medical implant devices with external monitoring capabilities.[8] Absent these monitoring capabilities, the Belos VR-T and Belos DR-T would be ordinary Belos VR and Belos DR implants in fit, form, and function, and would not require any type of authorization from the Commission, experimental or otherwise.[9]

Moreover, institutions and physicians participating in Biotronik's clinical studies are carefully screened, must attend a training seminar, and must sign Physician and Research Agreements providing for strict protocols on how clinical trials will be conducted.[10] Thus, Biotronik has tight controls on who uses the equipment and how it is

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[7] Medtronic Reply at 3.

[8] *See* 47 C.F.R. § 5.3(h); see also 47 C.F.R. § 5.5 (defining "experimental radio service"). The Belos VR-T and Belos DR-T implants serve entirely different medical purposes and therefore require separate clinical trials. The Belos VR-T monitors only a single chamber of the patient's heart while the Belos DR-T is a dual-chamber defibrillator. The Philos DR-T, for which Biotronik has an equipment authorization, is a pacemaker.

[9] It is commonplace for the Commission to issue experimental licenses specifically for testing enhancements of pre-existing products. *See, e.g., In re AirCell, Inc.*, Order, 17 FCC Rcd 1986, ¶1 (2002) ("AirCell also holds an experimental license allowing it to test enhancements to [its airborne cellular system].").

[10] Copies of the Physician and Research Agreements have been submitted to the Commission in a separate filing requesting confidential treatment of the agreements. *See* Letter to Mr. James Burtle, Office of Engineering and Technology, File No. 0223-EX-PL-2002 (Feb. 10, 2003) (Confidential Treatment Requested).

used. These conditions are inconsistent with the type of marketing campaign that Medtronic alleges is underway.

II. BIOTRONIK IS NEITHER SELLING NOR MARKETING UNAUTHORIZED RADIO DEVICES.

Medtronic insists that Biotronik is selling unauthorized equipment in contravention of the Commission's rules.[11] Again, Medtronic's accusation is false. The T chip and home monitoring equipment used with the Belos VR-T and Belos DR-T are authorized pursuant to Biotronik's experimental license grants and, as shown above, are the sole focus of Biotronik's clinical study. This equipment is not being sold to patients participating in experiments.[12] Biotronik receives no remuneration for either the T chip or the home monitoring equipment other than the valuable data collected from the use of the equipment in real-life situations.[13] Therefore, Medtronic's proposed license condition that Biotronik may not sell or lease this equipment is unnecessary.

Medtronic also accuses Biotronik of marketing unauthorized equipment, citing to Biotronik's press releases, trade press advertisements, and web site literature relating to

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[11] *See* Medtronic Reply at 3.

[12] As for Medtronic's assertion that Biotronik may not give away unauthorized equipment, Biotronik agrees that such statement is a proper interpretation of the regulations applicable to equipment authorized pursuant to Part 2 of the Commission's rules. However, the Belos DR-T and Belos VR-T are authorized pursuant to Part 5 of the Commission's rules, and, during the clinical study, patients must be furnished with the T chip and home monitoring equipment in order to conduct the experiments for which Biotronik has been authorized. Upon the conclusion of the two-year clinical study, Biotronik either will turn off the T chips and collect the home monitoring equipment distributed to patients, or will seek permanent Commission authorization for this equipment. *See* Medtronic Reply at 3.

[13] As explained in its Opposition, Biotronik does receive compensation for the implants used with the Belos VR-T and the Belos DR-T. This should hardly be unexpected, as these implants alone, without the T-chips and home monitoring system equipment, are identical in fit, form, and function to the Belos VR and Belos DR devices which do not offer transmitting capabilities and which Biotronik is permitted to use, market and sell without having to seek Commission approval. *See* Biotronik Opposition at 4-5.

the Belos VR-T and Belos DR-T.[14] These materials, however, do not support Medtronic's claim.

The press releases for the Belos DR-T and the Belos VR-T announce the devices' approval by the Food and Drug Administration ("FDA"). These press releases, however, make no suggestion that the devices currently are available for sale in the United States.[15] For example, the press release for the Belos VR-T reads in its entirety: "Home Monitoring ICD approved by the FDA. Belos VR-T, BIOTRONIK's single-chamber ICD with the innovative Home Monitoring function, has now been approved for the U.S. market. The FDA approval became effective on April 24th, 2002." These statements clearly are directed at FDA approval.

Biotronik's web site, which is based in Berlin, Germany, is available in both German and English, and is directed to the international community, not just physicians and patients in the United States. The web pages dedicated to the Belos VR-T and Belos DR-T provide a very short general description of the devices.[16] Neither device is available for purchase through the web site and Biotronik makes no representation that either device is available for sale in the United States. Nevertheless, to avoid misunderstanding, Biotronik will add a disclaimer to these web pages clarifying that neither device is currently available for sale in the United States.

Finally, the trade press advertisements Medtronic objects to are not device-specific, and again are directed to the global medical community. Neither the Belos DR-T nor the Belos VR-T devices is identified, described, or displayed in the advertisements, and Biotronik makes no representation that either of these devices is available for sale in the United States.[17]

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[14] *See* Medtronic Reply at 4.
[15] *See* http://www.biotronik.com/content/detail.php?id=1836.
[16] *See, e.g.*, http://www.biotronik.com/content/detail.php?id=2220#tdsmart (Belos DR-T).
[17] Moreover, the Philos DR-T, which offers the remote monitoring capabilities generally described in the advertisement, is subject to a valid equipment authorization and therefore
[...continued from last page]

III. THERE IS NO NEED TO REQUIRE A TWO-YEAR DISCLAIMER AS A CONDITION ON BIOTRONIK'S EXPERIMENTAL AUTHORIZATIONS.

Medtronic also asks the Commission to impose a two-year disclaimer on Biotronik's experimental authorization because, Medtronic claims, Biotronik "fully expects that the devices used in its two-year Home Monitoring experiment will continue beyond the two-year [license] period regardless of whether such operation is authorized."[18] Biotronik has made no such assertion and the proposed two-year disclaimer is unnecessary.

Contrary to Medtronic's distortion of Biotronik's statements, at this time Biotronik anticipates that the experiments currently being conducted on the T chip and home monitoring equipment of the Belos DR-T will be completed within the requisite two-year license period, as stated in its application. Biotronik's intent in referencing the renewal provision of the Commission's experimental licensing rules in its Opposition was to point out that all two-year experimental licensees, not just Biotronik, have the option of seeking renewal beyond the initial license term upon an adequate showing of need.[19]

Biotronik does not claim now that it will pursue renewal and it should not be required to make a showing of adequate need for renewal at this time. Medtronic, however, would deny Biotronik the option of renewal even before such opportunity has ripened. Moreover, Medtronic's proposed two-year disclaimer would deter patients and physicians from participating in the legitimate study of the Belos DR-T and thwart the very purpose of Biotronik's experimental authorization.

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may be marketed using such advertising without the Section 2.803(c) notice Medtronic proposes. *See* Medtronic Reply at 9.

[18] Medtronic Reply at 1.

[19] *See* Biotronik Opposition at 7; *see also* 47 C.F.R. 5.71(a).

IV. THE SCHEDULED TRANSMISSIONS OF BIOTRONIK'S MEDICAL IMPLANT DEVICES ARE PERMITTED UNDER THE COMMISSION'S RULES AS MEDICAL IMPLANT EVENTS.

Medtronic again raises its usual objection regarding Biotronik's Philos DR-T device, which is authorized and is not the subject of the experimental authorization that applies to the Belos VR-T and the Belos DR-T devices. This time, Medtronic claims that Biotronik has admitted that the Philos DR-T is unauthorized because this device uses an "automatic transmission feature."[20] Biotronik has made no such admission.

As Biotronik has explained previously, the alleged "automatic transmissions" are actually scheduled transmissions that are activated and controlled by a supervising physician and therefore qualify as medical implant events under the Commission's MICS rules.[21] Neither the patient nor any other person is able to program transmissions. The devices have no factory-default setting to transmit automatically and are shipped with their transmitting features turned OFF. Consequently, all transmissions, including those scheduled by the physician, require the intervention and supervision of a healthcare professional.[22]

It is interesting to note that, in the MICS rulemaking proceeding, Medtronic offered a definition of a "medical implant event" and an interpretation of the definition that is quite similar to Biotronik's interpretation. Medtronic proposed a definition of a

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[20] Medtronic Reply at 2. In its Reply, Medtronic once again has attempted to expand the scope of this proceeding beyond Biotronik's experimental authorization for the Belos DR-T. While Biotronik will answer all of Medtronic's unfounded accusations in this Response, Biotronik again asks the Commission to limit this proceeding to the experimental authorization for the Belos DR-T.

[21] *See* 47 C.F.R. § 95.628(b); *see also* 47 C.F.R. Pt. 95, Subpt. E, App. 1. (defining "medical implant event").

[22] *See* Biotronik Opposition at 8; *see also* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID. No. PG6BA0T (Apr. 8, 2002) at 3-5.

"medical implant event," which was adopted by the Commission without change and without comment.[23] In proposing that definition, Medtronic explained:

> [T]he definition simply recognizes . . . that the health care professional has the flexibility to determine what, for a particular patient, will be considered a medical implant event. Thus, if, in the medical judgment of a physician or other authorized health care professional, the patient's well-being requires the implant to transmit under certain conditions, **the health care professional may program the implant to recognize the conditions, which may include the passage of a preset period of time**.[24]

As can be seen, Medtronic's explanation of what qualifies as a "medical implant event" contemplates the scheduled transmission feature of Biotronik's implants.

Biotronik has submitted a Petition for Reconsideration of OET's Order concerning the Philos DR-T, clarifying that the alleged "automatic transmission" feature is in fact a medical implant event that is scheduled, programmed, and monitored by a physician.[25] Biotronik is confident that the Commission will so find when it acts upon Biotronik's Petition.

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[23] *See In re Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Implant Communications Service in the 402-405 MHz Band*, Report and Order, 14 FCC Rcd 21040, 21064 (1999).

[24] *In re Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Implant Communications Service in the 402-405 MHz Band*, WT Docket No. 99-66, RM-9157, Comments of Medtronic, Inc., Appendix A (Proposed Ruled) at 16 (Apr. 9, 1999) (emphasis added).

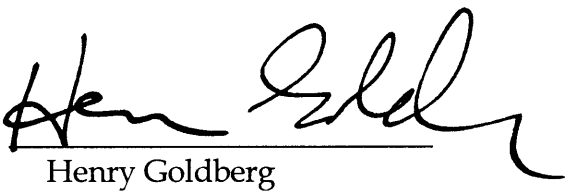
[25] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID. No. PG6BA0T (Apr. 8, 2002).

CONCLUSION

Medtronic continues to mischaracterize the nature and purpose of Biotronik's experimental authorizations in its latest effort to stifle Biotronik's advancements in medical implant technology. The Commission should recognize Medtronic's Petition for Reconsideration for what it plainly is—yet another disingenuous attempt to block Biotronik from developing potentially life-saving technology, motivated more by competitive animus than any genuine concern over harm to the public or potential interference to other MICS users.[26] Accordingly, Biotronik requests that the Commission dismiss or deny, with prejudice, Medtronic's Petition for Reconsideration.

Respectfully submitted,

BIOTRONIK, INC.

By: 

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[26] As Biotronik has explained in previous filings with the Commission, its devices that use home monitoring technology operate at ultra-low power levels, with a transmission duration of 80 milliseconds, and therefore present no realistic risk of harmful interference to MICS users. *See* Opposition of Biotronik, Inc., FCC ID PG6BA0T, Ref. No. 1300F2 (Apr. 23, 2002) at 3-4.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Response to Medtronic Reply was hand delivered, this 11th day of February, 2003, to each of the following:

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