Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

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

RESPONSE TO MEDTRONIC OPPOSITION

Biotronik, Inc. ("Biotronik"), by its attorneys, submits this Response to the Opposition of Medtronic, Inc. ("Medtronic") regarding Biotronik's above-captioned experimental authorization.[1] Once again, Medtronic has raised new arguments in its most recent Opposition, to which Biotronik responds briefly herein in order to set the record straight. For the reasons set forth below, Biotronik respectfully asks the Commission to reject Medtronic's Opposition and to dismiss or deny Medtronic's pending Petition for Reconsideration.

In its Opposition, Medtronic claims that Biotronik's Response to Reply, and accompanying Motion for Leave to Respond, were procedurally improper and should be rejected as unauthorized pleadings. While it is true that Commission's rules would not ordinarily permit the filing of additional responses with respect to this matter, the Commission long has recognized an exception to this rule if the opposing party raises new arguments or makes new factual allegations in its own reply.[2] Medtronic's reply did just that and, in the interest of fairness, Biotronik should have an opportunity to

---

[1] *See* Medtronic's Opposition for Motion for Leave to File a Response, File No. 0223-EX-PL-2002 (Feb. 21, 2003) ("Medtronic Opposition").

[2] *See In re Telefonica Larga Distancia de Puerto Rico, Inc.*, Memorandum Opinion, Order, Authorization and Certificate, 9 FCC Rcd 4041, n.15 (1994).

respond to the new arguments presented in Medtronic's reply. The same holds true for the instant response to Medtronic's Opposition. [3]

Medtronic first asserts that the Belos VR-T and DR-T devices are "fully integrated (and sealed)" and therefore Biotronik cannot argue that only the T-Chips contained in the devices require Commission authorization.[4] Medtronic has missed the point of Biotronik's argument. The fact is that the T-Chips contained in the Belos VR-T and DR-T can be turned "ON" or "OFF," thereby rendering transmissions from the implants impossible and converting the implants into ordinary Belos VR or DR devices.[5] It is the activation and use of these T-Chips for transmitting purposes on the 402-405 MHz band that require Commission authorization.[6] The devices are fully capable of fulfilling their function as defibrillators with their T-Chips deactivated, albeit it without the value-added feature of home monitoring. Contrary to Medtronic's implication, Biotronik does

---

[3] *See* Biotronik's Motion for Leave to Respond, File No. 0223-EX-PL-2002 (Feb. 11, 2003).

[4] *See* Medtronic Opposition at 4.

[5] To be clear, at present and without redesign of the firmware (*see* Biotronik's March 27th waiver request cited below), turning off the T-chip results in the deactivation of all three modes of transmission that the Belos VR-T and DR-T offer. These transmission modes cannot be deactivated in isolation from one another. The Commission previously has found that the event messaging and patient-activated transmission modes of Biotronik's devices satisfy the MICS rules. *See 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). Biotronik has sought a permanent waiver of the frequency monitoring requirements of the MICS rules for the third mode (scheduled periodic transmissions). *See In re Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules*, Request for Waiver (Mar. 27, 2003).

[6] In fact, it is OET's practice to authorize experiments on certain frequency bands, irrespective of the equipment used. *See, e.g.*, Experimental Actions, Public Notice, Report No. 349 (rel. Sept. 17, 2002) (WC2XYF, "New experimental to operate on 2400 MHz for development of air interface for Part 15 equipment."; WC2XVV, "New experimental to operate in 71-75.5 GHz for testing of point-to-point equipment."). Moreover, to accept Medtronic's "electrically integrated and sealed" argument would lead to absurd results. As an example, if a satellite operator received an experimental authorization to conduct testing with a single transponder on a certain frequency band, must the operator refrain from using the remaining transponders for other purposes just because the experimental transponder is "electrically integrated" with the whole satellite? The answer must be no, and the same should hold true for Biotronik's devices.

not need to demonstrate that the T-Chips can be physically removed from its implant devices to prove this point.[7]

Medtronic also continues to accuse Biotronik of conducting a "broad-based marketing campaign" of the Belos devices in violation of the Commission's equipment authorization rules.[8] To the contrary, Biotronik's web site and press releases are consistent with the Commission's rules. As previously explained, Biotronik's web site is based in Berlin, Germany and is intended for an international audience.[9] While it is impossible for Biotronik to know who is viewing its web site, it has nevertheless included a disclaimer on the web pages dedicated to the Belos VR-T and DR-T which clarifies that neither device is available for sale in the United States. In addition, despite Medtronic's selective use of isolated statements made in the press release for the Belos DR-T, it is apparent from the full text of the press release that its primary purpose was to announce FDA approval of the device.[10] In fact, the timing of the press release coincides with the date on which Biotronik received pre-market approval for the Belos DR-T from the FDA.[11]

Biotronik's magazine advertisements are also prepared by Biotronik's parent company in Berlin.[12] Like the web site and press releases, the ads are directed to the international medical community and do not identify either the Belos DR-T or VR-T

---

[7] In any event, Medtronic uses internal photographs of the Philos DR-T to make its argument. *See* Medtronic Opposition at Exhibit A. The circuitry of the Philos DR-T and the Belos VR-DT and DR-T devices is not comparable.

[8] *See* Medtronic Opposition at 6.

[9] *See* Biotronik's Response to Medtronic Reply, File No. 0223-EX-PL-2002 (Feb. 11, 2003) at 5.

[10] A copy of the full press release announcing FDA approval of the Belos DR-T is attached to this pleading.

[11] Biotronik received pre-market approval for the Belos DR-T on December 20, 2002, and its press release is dated December 31, 2002.

[12] The copyright notice on the advertisement supplied by Medtronic shows that it was produced by Biotronik GmbH & Co., which is Biotronik, Inc.'s German parent company. *See* Medtronic Opposition at Exhibit B.

devices by name.[13] Biotronik, however, did not examine the full text of the advertisement that Medtronic now has produced in full, suggesting the Biotronik's defibrillators are available with Home Monitoring technology in the United States.[14] Now that this discrepancy has been brought to Biotronik's attention, it will notify its Berlin offices and have the language removed from magazine advertisements until such time as Biotronik receives equipment authorization for the Belos VR-T and DR-T.

Finally, Medtronic now claims that Biotronik is conducting a limited market study of the Belos VR-T and DR-T devices because the clinical trials being conducted on the devices will help Biotronik "determine the market value of its RF circuitry."[15] As a result, Medtronic asserts that patients and healthcare professional should be fully informed that the devices are granted under experimental authorization.[16]

Biotronik's purpose in obtaining experimental authority for the Belos VR-T and DR-T, however, was to test the functionality of the T-Chip technology contained in the devices.[17] The fact that Biotronik is able to gauge the appeal of this technology to patients and physicians as a result of such testing does not convert the experiments into market studies. In accordance with the terms of Biotronik's experimental licenses, neither patients nor physicians are required to be informed of the experimental nature of the tests, and, in any event, medical personnel are informed of the experiments' protocols through the Physician Agreement that they sign.

---

[13] *See* Biotronik's Response to Medtronic Reply, File No. 0223-EX-PL-2002 (Feb. 11, 2003) at 5.
[14] *See* Medtronic Opposition at Exhibit B.
[15] *See* Medtronic Opposition at 8.
[16] *See* Medtronic Opposition at 9.
[17] The Belos VR-T is a single-chamber defibrillator, the Belos DR-T is a dual-chamber defibrillator, and the Philos DR-T is a pacemaker. Thus, the devices serve distinct medical functions and transmit different medical data. Medtronic's charge that Biotronik should already know the "market value" of the T-Chip technology in all these devices based on its marketing experience with the Philos DR-T is therefore without merit. *See* Medtronic Opposition at n. 26.

For the foregoing reasons, Biotronik requests that the Commission reject Medtronic's Opposition to Motion for Leave to File a Response and to dismiss or deny, with prejudice, Medtronic's Petition for Reconsideration.

Respectfully submitted,

BIOTRONIK, INC.

By: _____
Henry Goldberg
Joseph A. Godles

Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
(202) 429-4900

Its Attorneys

April 7, 2003

ATTACHMENT

Press Release for the Belos DR-T

BIOTRONIK

BIOTRONIK's Innovative Belos Dual-Chamber ICD with Exclusive Wireless Remote Monitoring Receives FDA Approval

Lake Oswego, OR, December 31, 2002; BIOTRONIK, Inc. announced today the commercial release of the Belos DR-T, the world's first dual-chamber, rate responsive implantable cardioverter defibrillator (ICD) that is able to instantly and automatically notify a physician when a patient has received life-saving therapy — without any involvement from the patient. This pioneering ICD reflects the company's commitment to innovative technology that helps improve patient outcomes while simplifying routines for healthcare providers.

The Belos dual-chamber family received market approval from the Food and Drug Administration (FDA) on December 20, 2002. The DR-T is the flagship device of the company's Belos family of ICDs, which also includes the VR-T, DR, and VR models.

Physicians are now able to offer patients with potentially life-threatening tachyarrhythmias a dual-chamber, rate responsive ICD with the most accurate AV discrimination feature on the market today. Instant notification of cardiac events is provided by the exclusive wireless remote monitoring feature called Home Monitoring. This system is fully automated, requiring no complicated patient-activated equipment or training.

Belos dual-chamber ICDs use SMART DetectionTM and RedetectionTM, the most accurate and reliable AV discrimination features available to distinguish life-threatening arrhythmias from normal heart rhythms. Appropriate discrimination is vital because inaccurate detections may result in the delivery of unnecessary therapy that can be painful and stressful for patients. SMART DetectionTM and RedetectionTM are 100% sensitive in detecting ventricular tachyarrhythmias and achieve an unsurpassed 94% specificity for discriminating supraventricular tachyarrhythmias (SVTs) from potentially lethal ventricular tachyarrhythmias.

Belos ICDs offer a full range of additional features, including a suite of anti-tachycardia pacing schemes (ATP). ATP therapy is emerging as an effective painless therapy option for treating certain types of arrhythmias. A unique Belos feature, called ATP Optimization, guarantees the delivery of the most effective ATP scheme based on prior successes. Using this exclusive feature, as well as the ATP on-screen histograms, healthcare providers are able to ensure patient safety and effective therapy.

Another key feature is unparalleled memory storage. Belos leads the industry in memory storage to assist the physician in clinical decision-making. Thirty minutes of dual-chamber or 60 minutes of single-chamber intracardiac electrogram recordings (IEGMs) are stored in the device, including separate IEGM recordings for SMART successes. In addition, these devices have an automatic 24-hour Holter feature built into the device that requires no external equipment.

The Belos family joins the existing market-released Tachos DR with Atrial Therapies in BIOTRONIK's growing line of rate-adaptive ICD products. The company continues to develop innovative products in its aggressive plans to meet the ever-changing demands of the U.S. cardiac rhythm market.

BIOTRONIK, Inc. is recognized worldwide as a complete provider of cardiovascular products of the highest quality and reliability. The company is committed to researching and developing new biomedical products. Its unmatched reliability record is the result of maintaining the highest standards in engineering and design. The company's U.S. headquarters are located in Lake Oswego, Oregon, and its worldwide headquarters are in Berlin, Germany.

Lake Oswego, Oregon
Contact: Tom Brown (800) 547-0394

Download:
Press Release: BIOTRONIK's Innovative Belos Dual-Chamber ICD with Exclusive Wireless Remote Monitoring Receives FDA Approval

CERTIFICATE OF SERVICE

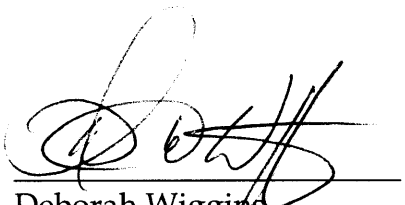
I hereby certify that a true and correct copy of the foregoing Response to Medtronic's Opposition was hand delivered, this 7th day of April, 2003, to each of the following:

Mr. David E. Hilliard *
Wiley Rein & Fielding LLP
1776 K Street, NW
Washington, DC 20006

Mr. James Burtle *
Chief
Experimental Radio Branch
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Mr. Bruce Franca *
Deputy Chief
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Mr. Bruce Romano, Esq. *
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554



Deborah Wiggins

* Courtesy copy sent via electronic mail.