Hand Deliver to Secretary:
236 Massachusetts Avenue, NE
Suite 110
Washington, DC 20002

Before the

Federal Communications Commission

Washington, DC 20554

ORIGINAL

In the Matter of Experimental Radio License Grant to Biotronik, Inc.

File No. 0223-EX-PL-2002

REPLY OF MEDTRONIC

Biotronik has confirmed each of the points Medtronic raised in its Petition for Reconsideration.

- Biotronik is marketing unauthorized devices in contravention of the Commission's rules;[1]
- Biotronik is using the Commission's experimental licensing program to market and sell unapproved medical implant devices that operate with automatic, periodic transmissions;[2] and
- Biotronik fully expects that the devices used in its two-year Home Monitoring "experiment" will continue to operate beyond the two-year period regardless of whether such operation is authorized.[3]

Medtronic respectfully submits this Reply to Biotronik's Opposition to the Petition for Reconsideration that Medtronic filed on January 2, 2003. In its Petition, Medtronic requested that the Commission reconsider the October 21, 2002, experimental license grant to Biotronik and, at a minimum, re-issue the grant with appropriate conditions. The stark admissions made by Biotronik in its Opposition revealing efforts to avoid the Commission's rules and procedures

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1 *See* Opposition to Petition for Reconsideration filed by Biotronik, Inc., File No. 0223-EX-PL-2002, Jan. 15, 2003 ("Biotronik Opposition") at 4-5, 7, 8.

2 *See id.*

3 *See id.* at 6-7.

merit rescission of Biotronik's experimental license and, at a minimum, call for adding appropriate restrictions to limit Biotronik's illegal marketing practices.

Biotronik's attempts to justify its egregious actions with novel and unsupported interpretations of the Commission's firmly established rules covering experimental licenses and marketing of unauthorized equipment confirm and heighten the concerns outlined in Medtronic's Petition. Statements made by Biotronik in its Opposition and in response to Commission inquiries during the instant application process require close Commission scrutiny.

I. Biotronik Concedes That It Is Marketing Devices In Contravention Of The Commission's Rules.

It is undisputed that Biotronik is actively marketing and selling RF devices that the Federal Communications Commission has determined do not comply with the agency's Part 95 MICS rules governing the operation of medical implant communications systems.[4] OET's March 8, 2002, Order "directed [Biotronik Inc.] to submit a modification or a new application for equipment authorization, deleting the automatic transmission option" for the Philos DR-T device.[5] Since Biotronik admits that it has done neither,[6] the Philos DR-T device is unauthorized and may not be sold or offered for sale.[7] In addition, Biotronik admits that the Belos VR-T and DR-T devices, which also contain the automatic periodic transmission feature, are unauthorized.[8]

Biotronik provides no explanation of why it has ignored the Commission's directive to modify its equipment by "deleting the automatic transmission option," and provides no support

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4 *See* Biotronik Opp. at 7, 8; FCC Letter Order, Mar. 8, 2002, from Bruce A. Franca, OET, to David E. Hilliard, counsel for Medtronic, and Mark Johnson, Biotronik, at 3 ("OET Letter Order").

5 OET Letter Order at 3.

6 *See* Biotronik Opp. at 8.

7 *See* 47 C.F.R. § 2.803.

8 *See* Biotronik Opp. at 7.

for its novel argument that it "should not be required to cease marketing the [Philos DR-T] device while the Commission rules on its [reconsideration and waiver] request."[9]

Biotronik is using the Commission's experimental license authorizations as a shield for the marketing and sale of the Belos VR-T and DR-T devices.[10] Biotronik claims that under its experimental authorizations it may charge patients for the implanted device, as long as it does not charge patients for the implant's "transceiver system or the wireless communications technology" that is integrated into the single compact unit.[11] In so doing, Biotronik is dissecting a single integrated device that is subject to the Commission's rules into two parts – one part that it argues is not subject to the Commission's rules and another part that is subject to the Commission's rules – with the intent to market the integrated device.[12] This is absurd.

Biotronik is unable to cite to any Commission precedent for this novel rule interpretation. Indeed, Biotronik may not unilaterally redefine the Commission's rules in any manner it wants in order to justify the sale of unauthorized equipment. Even if such device dissection were allowed, Biotronik is giving away the transceiver system for free, and the FCC's rules prohibit the giving away of unauthorized equipment.[13] Moreover, the Commission requires clear notice whenever and wherever unauthorized devices are displayed or advertised.[14] Medtronic has been unable to

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9 Biotronik Opp. at 8. Biotronik did not request a stay of the Commission's March 8, 2002, letter order and none was granted by the Commission based on its own motion.

10 *See* Biotronik Opp. at 4-5.

11 *See* Biotronik Opp. at 5. This explains how Biotronik is attempting to recoup the roughly $3 Million in foregone revenue, as Medtronic estimated in the Petition. *See* Petition at 7-9.

12 Biotronik's scheme would allow any RF device manufacturer to market and sell unauthorized equipment with an experimental license grant. Even if a device included only an RF transmitter and a battery, Biotronik would claim that sale of the battery is allowed.

13 *See* Petition at 9 n.22 (citing FCC interpretation of Section 2.803).

14 *See* 47 C.F.R. § 2.803(c).

find the required notice on any Biotronik advertisement or display for any of these still unapproved RF devices.

Biotronik also states that the Philos DR-T "is being marketed," but claims that the "Belos DR-T and Belos VR-T are subject to their respective experimental authorizations and are not being marketed."[15] However, a review of Biotronik's website literature, press releases and trade press advertisements shows that Biotronik is marketing and advertising each of the devices in exactly the same way.

The website literature for each of the devices promotes the automatic periodic transmission feature and does not include the required notice for advertising unauthorized equipment required by Section 2.803(c) of the FCC's rules.[16] As with the press releases announcing the FDA's approval of the other two units, the recent press release advertising the Belos DR-T touts the Home Monitoring capability that "Physicians are now able to offer."[17] None of the press releases includes the required FCC notice. And a recurring medical trade press ad from Biotronik announces that its Home Monitoring implants send messages "automatically ... with no patient intervention ... at any specific time or frequency that you decide."[18] The ad makes no distinction between – and in fact, does not identify – any of the three implants with

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[15] Biotronik Opp. at 7.

[16] *See* Petition at 4 n.9 (citing Biotronik website literature for Philos DR-T and Belos VR-T). Indeed, since Medtronic filed the Petition, Biotronik added detailed website literature for the Belos DR-T also advertising the automatic periodic transmit feature. See Biotronik Website Product Description for the Belos DR-T Dual-Chamber ICD with Home Monitoring, *available at* <http://www.biotronik.com/content/detail.php?id=2220>, *last accessed* Jan. 20, 2003.

[17] *See* "BIOTRONIK's Innovative Belos Dual-Chamber ICD with Exclusive Wireless Remote Monitoring Receives FDA Approval," Jan. 6, 2003, *available at* <http://www.biotronik.com/content/detail.php?id=2204>, *last accessed* Jan. 20, 2003. *See also* Petition at 6 n.15.

[18] *See* Exhibit 1 to Petition. Instead of following the Commission's directive to delete the automatic periodic feature, Biotronik has chosen to ramp up marketing efforts for its unauthorized implant devices.

Home Monitoring technology. Thus, any physician or cardiac patient viewing these ads and Biotronik's other marketing literature would think that all three devices are available for sale and would not know that the Commission has yet to authorize their operation.[19]

Accordingly, Biotronik is improperly marketing and offering for sale all three devices on the same basis. Biotronik's claim that it is marketing the Philos DR-T device, but not marketing the Belos DR-T and VR-T devices, is a distinction that exists only in Biotronik's Opposition.

II. Biotronik Admits That It Is Using The Commission's Experimental Licensing Program To Market Unauthorized Devices And Fully Expects That The Limited Experimental Study Will Extend Well Beyond The Two-Year Grant Even If Continued Operation Is Not Authorized.

The Opposition makes clear that Biotronik is running its grand-scale "experiment" to drum up demand for its Home Monitoring products.[20] Biotronik explains that it will request renewal of its experimental authority to permit continued operation of unauthorized devices and continue to market and sell RF implants (with the exception of the device's RF transmitter which will be given away).[21]

Thus, the statement in Biotronik's application that "The entire study will have a duration of less than the 2 years allotted by the experimental license"[22] is not credible. In making this disingenuous statement, Biotronik was likely trying to avoid the Commission's "License Period" requirement that "An applicant desiring to apply for a 5-year license must provide justification

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19 And further that their operation is limited to the conditions attendant to an experimental license – conditions that are at odds with the normal operation and life expectancy of a medical implant.

20 *See* Biotronik Opp. at 8. The marketing rules are designed to provide flexibility in the development of products while preventing the creation of demand for products that cannot be approved under the current rules. Biotronik's approach runs counter to this policy.

21 *See* Biotronik Opp. at 7-8.

22 *See* Exhibit 1 to Biotronik application at 2.

for its need for a license of that duration."[23] Such an added justification is not required when requesting a limited two-year experimental authorization.[24]

Biotronik's perpetual renewal theory combined with its belief that it can sell unauthorized devices incorporating unauthorized RF transmitters (as long as it does not "sell" the RF transmitter) reveal a scheme whereby Biotronik is attempting to legalize the sale of unauthorized RF devices. Biotronik's experimental license campaign is therefore a misguided – and illegal – marketing scheme to garner support for a technology that has already been declared by the Commission as non-compliant.

Given the evidence of Biotronik's marketing onslaught conducted under the guise of "experimentation," it is also clear why Biotronik continues to maintain that it is not running a "limited market study."[25] The Commission's rule for limited market studies in Section 5.93 imposes conditions that Biotronik does not wish to follow. When conducting limited market studies, "[a]ll transmitting and/or receiving equipment used in the study shall be owned by the licensee."[26] Biotronik plans to sell its devices. Also, "[t]he licensee is responsible for informing anyone participating in the experiment that the service or device is granted under an experimental authorization and is strictly temporary."[27] Biotronik's desire to withhold the truth

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[23] 47 C.F.R. § 5.71. Section 5.71(b) states "A license will not be granted for a period longer than that which is required for completion of the experimental project." Thus, the instant experimental license grant should not be renewed.

[24] In this case however, even a five-year experimental license term would not preclude the need for an extension, as the lifetime of the implant could exceed 5 years. *See* Petition at 1 n.2.

[25] *See* Biotronik Opp. at 6.

[26] 47 C.F.R. § 5.93(a).

[27] 47 C.F.R. § 5.93(b).

from cardiac patients and administering medical professionals can hardly be deemed to be informed consent for treatment.[28] Such disclosure is critically important.

In addition, during the experimental license application, Biotronik failed to answer the FCC's inquiry into whether it will sell or lease the 300 Belos DR-T devices to be implanted into human patients. FCC staff asked Biotronik if it was conducting a "market study test," and "what financial or contractual arrangement will Biotronik Incorporated have with the participants, customers and/or general public."[29] Biotronik replied that "less than 20 units" would be used as "marketing demonstration units" and that it was "not running a marketing study with [the] devices or collecting any fees from potential customers."[30] We now know that Biotronik is running a market study with the 300 devices it plans to implant pursuant to the Commission's experimental authority and that Biotronik is planning to sell every one.[31] This blatant flouting of the Commission's rules must be closely scrutinized and appropriately addressed.

The rules for limited market studies under the Commission's experimental license regime are necessary when conducting a study where RF devices are marketed to members of the public who will use and rely on the devices. There is ample evidence that these rules apply here. Indeed, Biotronik is implanting experimental devices into consenting cardiac patients. These individuals and their attending physicians need to appreciate fully the terms and conditions of

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[28] *See* Biotronik Opp. at 6. Biotronik's claim that providing such critical information to cardiac patients and physicians is "not in the public interest" is astonishing. *See id.*

[29] Email, Oct. 9, 2002, from John Kennedy, FCC staff, to Mark Johnson, Biotronik's Director of Marketing.

[30] Email, Oct. 10, 2002, from Mark Johnson, Biotronik's Director of Marketing, to John Kennedy, FCC staff. *See also* Petition at 8, 9 n.23. The Commission also asked whether "Biotronik will retain ownership of the devices during and after the market study test." Email, Oct. 9, 2002, from John Kennedy to Mark Johnson. Biotronik did not completely answer this question, but its Opposition makes clear its intentions.

[31] *See* Biotronik Opp. at 4-5.

Biotronik's study in order to make an informed decision. They must be told that the devices may not be sold or given away because the Commission has authorized the implant's Home Monitoring feature only on an experimental basis.

As Medtronic explained in the Petition, the MICS rules were designed to avoid the disruption of life critical transmissions by including frequency-agile implanted transceivers, channel sensing, and a listen before transmit protocol to limit interference among implanted devices operating in close proximity, such as in a medical facility or nursing home.[32] These are key features that the transmit-only Biotronik implants do not have. Thus, scheduled transmissions by a Biotronik implant close to MICS-compliant implant could disrupt established MICS communications between a physician and critically ill cardiac patient (or even disrupt receipt of non-frequency agile transmissions from a second non-compliant Biotronik unit).

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It is firmly established that Biotronik may not legally sell, lease, or give away any devices that the Commission has not approved. Based on the intended application, longevity and operation of a medical implant, one must question whether it is in the public interest to issue an experimental license to an applicant whose primary objective to market non-compliant devices and consciously decide to withhold this information from attending physicians and patients in which the devices are implanted. Any experiment involving the surgical implantation of these devices must include an explanation by the physician to the patient that the devices are not being sold, leased, or given away, because the FCC has not authorized the devices for operation in the United States. Biotronik must inform all participating physicians and patients that they are part

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32 *See* Petition at 3 n.5.

of a study that is proceeding under a two-year experimental license.[33] The FCC should also include a condition that, once the license expires, the experimental implants must cease use of the MICS band unless certification of the implants has been granted showing compliance with the Part 95 MICS rules.

CONCLUSION

Medtronic respectfully requests that the Commission rescind the experimental license grant to Biotronik or, at a minimum, impose these conditions:

1) Biotronik may not sell or lease, or offer for sale or lease, or give away any devices that are not authorized by the Commission, including the Belos DR-T and VR-T defibrillators and the Philos DR-T pacemaker – each of which operates with automatic periodic transmissions and each of which remains unauthorized by the FCC; the foregoing prohibition includes all devices that are implanted pursuant to Biotronik's experimental license authorizations;

2) Biotronik must inform all medical health care professionals and implant patients who participate in Biotronik's "experimental study" that the Biotronik implant devices are authorized for operation based on a "two-year experimental FCC license;" the operation of transmissions in the MICS band must cease once the two-year period expires unless such device operation is approved under the MICS rules; and,

3) All Biotronik literature concerning any of the above-identified devices, including trade magazine ads, press releases, and Internet website pages advertising the products, must contain a notice in accordance with Section 2.803(c) of the Commission's Rules that the products are not available for sale or lease, until the requisite authorization has been granted by the FCC.

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[33] According to Biotronik, "The protocol study requires two years to execute upon receipt of the experimental license, upon which time the results will be made commercially available and confidentiality will no longer be required." Email (Request for Confidentiality Item 8 of 9), Oct. 10, 2002, from Mark Johnson, Biotronik's Director of Marketing, to John Kennedy, FCC staff. Again, in its Opposition, Biotronik admits that the statements in the experimental application are wrong, and now requests confidential treatment beyond the two-year term. *See* Biotronik Opp. at 7 n.22. Medtronic requests that the Commission hold Biotronik to the representations in its application and make public Biotronik's entire experimental license application upon expiration in November 2004. *See* Petition at 9-10 n.25.

Biotronik's unequivocal admission that it has been and continues impermissibly to market and sell unauthorized devices only underscores the need for close FCC review of this application.

Respectfully submitted,

MEDTRONIC, INC.

By: _____

David E. Hilliard
John W. Kuzin
Of
Wiley Rein & Fielding LLP
1776 K Street, NW
Washington, DC 20006
Its Attorneys

January 22, 2003

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on the date printed below, the foregoing REPLY OF MEDTRONIC was delivered by First Class U.S. mail to the persons listed below.

Mr. Mark Johnson
Director, U.S. Marketing
Biotronik, Inc.
6024 SW Jean Road
Building B
Lake Oswego, OR 97035

Henry Goldberg, Esq.
Goldberg, Godles, Wiener & Wright
1229 19th Street, NW
Washington, DC 20036
Counsel for Biotronik, Inc.

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

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

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

January 22, 2003

Rheatte E. Brighthaupt

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* Courtesy copy via electronic mail.