Before the

Federal Communications Commission

Washington, DC 20554

In the Matter of Experimental Radio License Grant to Biotronik, Inc.	File No. 0223-EX-PL-2002

PETITION FOR RECONSIDERATION

Medtronic, Inc., respectfully asks the Commission to reconsider the October 21, 2002, experimental radio license grant to Biotronik, Inc., for operation of 400 implantable medical devices in the Medical Implant Communications Service (MICS) between 402 and 405 MHz.[1] For reasons explained in this petition, the grant issued under FCC File Number 0223-EX-PL-2002 should be reconsidered and, at a minimum, re-issued with the following conditions:

1) Biotronik may not sell or lease, or offer for sale or lease, any devices that are not authorized by the Commission, such as the Belos DR-T defibrillator (specifically mentioned in the above-identified experimental license application), the Belos VR-T and the Philos DR-T pacemaker – each of which operates with automatic periodic transmissions and each of which remains unauthorized by the FCC;

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 any non-compliant features, such as automatic periodic transmissions, must cease once the two-year period expires;[2] and,

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[1] Medtronic, one of the leading manufacturers of medical implant devices, develops transceivers that operate in the Medical Implant Communications Service (MICS) band. As such, Medtronic has standing to submit this petition for reconsideration.

[2] The useful lifetime of implanted defibrillators extends significantly beyond the two-year experimental period; typical defibrillator batteries last over five years. *See* Biotronik Specification for Belos VR unit (5.6 year longevity with quarterly shocks); *see also* "Guidance

3) All Biotronik literature concerning any of the above-identified devices, including trade magazine ads,[3] press releases, and Internet website pages advertising the products, must contain a notice in accordance with Section 2.803 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.

As explained below, statements made by Biotronik during the instant experimental license application process and aggressive marketing of products that the Commission has not authorized necessitate these conditions.

BACKGROUND

On November 29, 1999, the Commission established the Medical Implant Communications Service (MICS) for operation in the 402 to 405 MHz frequency band.[4] The MICS rules provide for low-power wireless communications for sending diagnostic and therapeutic data between an external MICS controller and an implanted medical device, such as a cardiac pacemaker or defibrillator. The 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 between implanted devices operating in close proximity, such as in a medical facility or nursing home. Indeed, the limited number of channels in the MICS band requires that established communications between a physician and implant patient are not pre-empted by non-emergency transmissions from other devices, which

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On The Use Of Implantable Cardioverter Defibrillators For Arrhythmias," National Institute for Clinical Excellence, Technology Appraisal Guidance No. 11, Sept. 2000 at 3 (battery life for implanted defibrillator can last "up to nine years").

[3] The PACE Journal ad announces: "Biotronik implants send messages ... [a]utomatically ... at any specific time or frequency that you decide."). *See* PACE, Aug. 2002, Vol. 25, No. 8 at vii *and* Nov. 2002, Vol. 25, No. 11 at vii (copy attached as Exhibit 1). PACE (Pacing And Clinical Electrophysiology) is the Official Journal of (1) The North American Society of Pacing and Electrophysiology and (2) The International Cardiac Pacing and Electrophysiology Society.

[4] In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, 14 FCC Rcd 21040 (Nov. 29, 1999).

could delay emergency care with potentially fatal consequences.[5] In this respect, the MICS rules presaged the recent findings by the Spectrum Policy Task Force that efficient, interference-free spectrum sharing by multiple wireless communications technologies can be facilitated by intelligent transceivers that manage the frequency and time of their transmissions so as to avoid using the same frequency at the same time as other devices.[6]

On April 23, 2001, Biotronik received a Grant of Equipment Authorization, FCC ID: PG6BAOT, for its Philos DR-T implantable medical device that can only transmit on the single frequency of 403.6 MHz.[7] The transmit-only Philos unit is configured to automatically and periodically transmit at 403.6 MHz and does not perform any channel sensing prior to transmitting. Medtronic requested that the FCC set aside the authorization and deny the application because the Biotronik device did not comply fully with the agency's rules.

In a Letter Order, the Office of Engineering and Technology agreed with Medtronic that the Philos DR-T device failed to comply with FCC regulations because it generates automatic periodic transmissions without first monitoring the channel. OET ordered Biotronik Inc. to submit a modified or new equipment application "deleting the automatic transmission option."[8]

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[5] Consider, for example, the situation where a defibrillator is being implanted. A MICS communication channel will typically be obtained at the start of the surgical procedure. If the patient goes into ventricular fibrillation and it becomes necessary for the physician to initiate emergency defibrillation therapy, the MICS system must be able to send the surgeon's command immediately. While back-up transthoracic defibrillators are available, critical time is lost in resorting to this. Transmit-only Biotronik devices operating in the area could disrupt the communication channel. If disrupted, a MICS compliant system would have to search for a free channel, if there is one. (It is hardly unusual to have multiple ICD patients in close proximity.)

[6] *See* Spectrum Policy Task Force Report, ET Docket No. 02-135, Nov. 2002, *available at* <http://www.fcc.gov/Daily_Releases/Daily_Business/2002/db1115/DOC-228542A1.doc>.

[7] The grant was reissued on May 5, 2002, to correct the output power originally specified.

[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 (hereinafter "OET Letter Order").

Rather than follow the Commission's Order, Biotronik took a more aggressive route. First, Biotronik filed a petition to reconsider the FCC's clear directive to remove the implant's automatic periodic transmit option. Biotronik also requested a waiver to allow continued operation in the automatic periodic transmit mode. Remarkably, without waiting for a decision from the Commission on its reconsideration and waiver requests, Biotronik proceeded to market equipment with an automatic periodic transmission feature in contravention of OET's March 8, 2002, decision.[9] In addition, the FCC Equipment Authorization records for FCC ID: PG6BAOT do not show any request for modification of the original application by Biotronik Inc. Nor do those records show any additional grants of equipment authorization issued to Biotronik Inc. under grantee code PG6 for any device similar to FCC ID: PG6BAOT that does not incorporate the automatic transmission provision. Thus, as a matter of public record, to date, Biotronik Inc. has not complied with OET's Letter Order to delete the automatic operation provision from their implantable products using their proprietary "Home Monitoring" technology.[10]

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[9] Biotronik's marketing literature makes clear that these devices continue to operate by sending automatic periodic transmissions. According to Biotronik, the "Philos DR-T [pacemaker's] additional Home Monitoring feature enables the pacemaker to send: Periodic Message (the time period initiates the message)." *See* Biotronik Website Product Description for the Philos DR-T Dual-Chamber Pacemaker with Home Monitoring, *available at* <http://www.biotronik.com/content/detail.php?id=1783> *last accessed* Dec. 30, 2002.

Also, the "Belos VR-T is the world's first ICD with the Home Monitoring function [that] automatically transmits data ... as a Periodic Report (once every 24 hours)." *See* Biotronik Website Product Description for the Belos VR-T Dual-Chamber Pacemaker with Home Monitoring, *available at* <http://www.biotronik.com/content/detail.php?id=1839> *last accessed* Dec. 30, 2002.

[10] In addition, the User Manual for Biotronik's medical implant receiver/cell-phone submitted with its recent application for FCC equipment authorization states that "[t]he doctor has adjusted your implant so that it transmits periodic messages at a certain time and at periodic intervals." Brochure for Patients Using the Home Monitoring Patient Device, at 14, *submitted with* Biotronik Application for Equipment Authorization, FCC ID No. PG6RUCM200. Moreover, the User Manual makes clear that for patients with implanted defibrillators, the automatic periodic transmission mode is the only available mode of operation. *See id.*

Now, in the application at hand, Biotronik has requested approval for "experimental" authorization for a "study" that will allow implantation of 300 Belos DR-T devices into human patients.[11] This latest experimental application and resulting license follow on the heels of another experimental license issued to Biotronik in April 2002, which authorized the operation of 200 unspecified models of unapproved implantable devices.[12]

With this pleading, Medtronic is asking the Commission to reconsider Biotronik's experimental licenses and use its discretionary authority to address the most recent request. Medtronic requests that the Commission clearly delineate the limits and bounds of Biotronik's experimental authorization, in light of Biotronik's marketing flurry that conceals the fact that the

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[11] The instant application requests authorization for 400 units: 300 to be implanted in human patients, and 100 for R&D prototypes, validation units and working demonstration systems. While Biotronik's website does not contain detailed information on the specific medical implant device identified in the application (*i.e.*, the Belos DR-T), it does contain detailed descriptions on the Belos VR-T and Philos DR-T devices. Based on the publicly available information, it appears that –like the Belos VR-T and Philos DR-T devices – the Belos DR-T unit also operates with automatic periodic transmissions. *See* Exhibit 1 to Biotronik application ("Communication starts with the implant, which activates an RF transmitter at 403.65 MHz ... . The patient is equipped with a receiver centered at 403.65MHz ... to accept the incoming data. ... Each transmitter will provide less than or equal to 10 transmissions per day."). The transmitter in the Belos DR-T unit, an ICD that can store electrocardiograms, appears to be very similar to that in the other units. *See also* "Press Release: First Implantations of Belos DR: A Novel Dual-Chamber ICD System Offering Unique Diagnostic Tools" *available at* <http://www.biotronik.com/content/detail.php?id=1446> *last accessed* Jan. 2, 2003 ("The ICD system will also be available with Home Monitoring (Belos DR-T), which allows for remote patient management.").

[12] File number 0062-EX-PL-2002. Biotronik's experimental license requests indicate that the radio links for its implanted devices with Home Monitoring are very similar. There are no differences in the transmission parameters specified in either request for the experimental licenses. Both operate in the 402 to 405 MHz band, both specify a maximum power of 25 μW, a 40 kHz bandwidth with a maximum deviation of 190 kHz, both specify that transmission is to a receiver connected to a telephone line for retransmission to a Biotronik control center, and both requests have language strongly suggesting that the implant "automatically" initiates transmission. In fact, but for their automatic-periodic transmission capability, these devices would likely be eligible for certification under the FCC's MICS Rules. Thus, the requests appear to be an attempt to market and/or garner support for a technology that has already been declared by the Commission as non-compliant.

FCC has not authorized the devices, lest the experimental authority be used – or even considered – as "cover" for impermissible marketing, including the sale or lease of the devices.

PETITION FOR RECONSIDERATION

Biotronik's Marketing Of "MICS" Implants That Operate With Automatic Periodic Transmissions Is A Clear Violation Of The FCC's Order.

OET's March 8, 2002, Order regarding the Biotronik Philos DR-T device makes clear that "automatic signal" transmissions are "not within the letter of the Commission's [MICS] Rules."[13] The Commission "directed [Biotronik Inc.] to submit a modification or a new application for equipment authorization, deleting the automatic transmission option."[14] In the nine months that have elapsed since OET's Order, the public record shows that Biotronik Inc. has done neither. In addition, Biotronik appears not to have obtained an equipment authorization for its Belos devices with home monitoring capability. As such, the Philos DR-T device as well as the Belos VR-T and DR-T devices remain unauthorized.

In spite of this, Biotronik's marketing and press releases indicate that the devices are available for sale. According to its website, the Belos VR-T and Philos DR-T units are "approved for the U.S. Market" now that the FDA has okayed them.[15] Significantly, Biotronik

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[13] OET Letter Order at 3. The Belos DR-T, which is mentioned in Exhibit 1 to Biotronik's experimental license application, the Belos VR-T and the Philos DR-T devices all generate automatic periodic transmissions. *See* notes 9 & 11, *supra*.

[14] *See id.* Biotronik filed a petition for reconsideration of the Commission's Order and has, alternatively, requested a waiver of the Order to allow its automatic transmissions. *See* Biotronik, Inc. Petition for Reconsideration or Waiver, FCC ID: PG6BA0T, Ref. No. 1300F2, Apr. 8, 2002. The Commission has not issued any decisions regarding either the petition or the waiver request. Thus, Biotronik devices with the automatic periodic transmission feature remain unapproved for lease or sale within the United States. *See* 47 C.F.R. § 2.803(a).

[15] *See* "Home Monitoring Pacemaker now also Approved by the FDA" *and* "Home Monitoring ICD approved by the FDA" *available at* <http://www.biotronik.com/content/detail.php?id=1448>, *last accessed* Dec. 30, 2002. *See also* "BIOTRONIK Announces FDA Approval of the Belos VR-T Implantable Cardioverter

makes no mention – in any press release or in any website advertisement – that the FCC has not authorized the devices with automatic periodic transmission capability. Biotronik also fails to note that, without the FCC's approval, the Belos VR-T / DR-T and the Philos DR-T may not be sold or leased in the U.S.

The Experimental License Grant Should Make Clear That (1) Biotronik May Not Sell or Lease Any Devices That The FCC Has Not Authorized, and (2) Biotronik Must Inform All Participants In Its Experimental Study That The Devices To Be Implanted Are Authorized Under a "Two-year Experimental FCC License."

Biotronik's application fails 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. When FCC staff asked Biotronik if it was seeking limited market study authority, it responded 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."[16] This deflection of the Commission's inquiry begs the question as to the sale, lease or give-away of the 300 units to be implanted. Indeed, based on a conservative price of $10,000 per unit,[17] Biotronik's "experiment" represents $3.0 million dollars in foregone revenue for the devices alone.

Defibrillator with Home Monitoring Technology," May 3, 2002 ("BIOTRONIK, Inc. announced today that **the [FDA] has approved the commercial release** of the Belos VR-T Implantable Cardioverter Defibrillator (ICD) with Home Monitoring technology. This approval follows the recent release of the Philos DR-T pacemaker.") (emphasis added) *available at* <http://www.biotronik.com/content/detail.php?id=1867>, *last accessed* Dec. 30, 2002; *and see* "BIOTRONIK Announces First U. S. Implantation of the New Belos VR-T ICD with Home Monitoring," May 3, 2002 ("BIOTRONIK's Home Monitoring System is already proving its value to clinicians in the **currently released** Philos DR-T pacemaker.") (emphasis added) *available at* <http://www.biotronik.com/content/detail.php?id=1866>, Dec. 30, 2002.

[16] Email, Oct. 10, 2002, from Mark Johnson, Biotronik's Director of Marketing, to John Kennedy, FCC staff.

[17] The price for a defibrillator unit such as the Belos DR-T is likely much greater than $10,000 U.S. dollars; the price for a pacemaker is less. *See The Globe and Mail*, Nov. 11, 2002 (price of Philos DR-T pacemaker is $7000 Canadian dollars, which is about $4500 U.S. dollars).

This large amount of foregone revenue, coupled with Biotronik's share of the U.S. defibrillator market raises serious concerns that these authorizations may be a cover for impermissible marketing of the devices. Based on actual 2001 industry data, the number of units covered by Biotronik's experimental applications is almost equal to the total number of defibrillators that Biotronik could expect to sell next year.[18] These facts warrant close FCC review of the instant application.

It is not surprising that Biotronik routinely conducts experimental product trials for the purpose of drumming up demand and developing market share.[19] However, in typical product trials, Biotronik uses less than 20 devices, not hundreds, and runs the trial for weeks, not years.[20] Couple this with Biotronik's June 2002 announcement that its Home Monitoring technology is "100% reliable"[21] makes one wonder whether such a grand-scale FCC experiment with hundreds of implanted devices is even necessary. (An obvious benefit in running such a grand "experiment" is to drum up demand for its Home Monitoring products.)

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18 Biotronik has less than a 1.1% share of the total U.S. defibrillator market, which equates to less than 759 units. *See* Morgan Stanley Equity Research, North America, Hosp. Supplies & Medical Technology, Oct. 8, 2002 at 28 (2001 actuals for "Other" category which includes "primarily Biotronik and ELA/Sorin").

19 *See* "Biotronik Will Launch Telemetry Pacemaker Following Marketing Trial," *The Gray Sheet*, Oct. 15, 2001, Vol. 27, No. 042, at 5 ("Biotronik will conduct a 90-day marketing trial of its BA03 pacemaker and Home Monitoring System before fully launching the products in the U.S. ... [O]ne of the goals of the trial is to build demand for the device.").

20 *See id.* (FDA submission "based on a 14-day trial in which 15 patients carried the BA03 [pacemaker test unit] strapped to their bodies").

21 ""Telemedicine: Will Follow-ups Ever Be the Same? Biotronik's Home Monitoring System" June 6, 2002 ("clinical results have shown that the Home Monitoring System is 100% reliable") *available at* <http://www.biotronik.com/content/detail.php?id=1911>, Dec. 31, 2002.

It is firmly established that Biotronik may not legally sell, lease, or give away any devices that the Commission has not approved.[22] Accordingly, any experiment involving the surgical implantation of these devices must include an explanation to the physician and 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.[23] Further, Biotronik must ensure that all participating physicians and patients understand that they are part of a "study" that is proceeding under a "two-year experimental license."[24]

Indeed, Biotronik's application does not even address what will happen with the implanted devices following the two-year period.[25] In fact, the useful life of these devices

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[22] OET Staff recently explained, "The Commission has interpreted these rules [47 C.F.R. §§ 2.803 and 2.1204] to include give-aways, as marketing since the rules are for protecting licensed radio services from interference and the interference issue is pertinent despite the cost of the device." Ray LaForge, Chief, OET Measurements and Calibration Branch. *See* FCC Rule Interpretations Database, Item No. 20011207-002, *available at* <https://gullfoss2.fcc.gov/prod/oet/index_ie.html>.

[23] The publicly available information contains an unacceptable response from Biotronik to the staff inquiry into whether Biotronik "will retain ownership of the devices during and after the market study test." Email, Oct. 9, 2002, from John Kennedy, FCC staff, to Mark Johnson, Biotronik's Director of Marketing. Biotronik merely states that it will not "collect[] any fees" for the 20 or so devices used for "marketing demonstration" purposes. Email, Oct. 10, 2002, from Mark Johnson, Biotronik's Director of Marketing, to John Kennedy, FCC staff. Biotronik fails to address the Commission's inquiry as to the sale, lease or distribution of the 380 other units. Under Section 5.65(b), failure to provide the requested information constitutes a defective application that may be returned to the applicant.

[24] Section 5.53(a) provides that "No radio transmitter shall be operated in the Experimental Radio Service except under and in accordance with a proper station authorization granted by the Commission." Thus, once the experimental license grant expires, operation must cease. Accordingly, the FCC should include a condition that, once Biotronik's experimental license expires, any implants must cease using automatic periodic transmissions and comply with the MICS rules if operation in the MICS band is to continue.

[25] Biotronik has requested limited confidential treatment of the details of the experiment. Thus, it is possible that this information was submitted. If so, there would be no basis for treating such basic information as confidential even if other details of the experiment may merit such treatment.

extends well beyond the two-year "experimental period."[26] The operation of non-compliant devices beyond this period contravenes the purpose and spirit of the Commission's experimental licensing program as well as the FCC's Letter Order. Thus, Biotronik must be ordered to cease non-compliant automatic periodic transmissions from all devices once the two-year experimental period has expired, and any continued operation must comply fully with the MICS rules.

In addition, given Biotronik's misleading marketing campaign, Medtronic requests that the FCC, at a minimum, condition the experimental license grant by requiring that all Biotronik literature distributed with the Belos VR-T, the Belos DR-T and the Philos DR-T devices, including press releases, trade magazine ads, and Internet website pages advertising the products, contain a notice that the products are not authorized for operation by the FCC, unless and until the requisite authorization has been granted by the agency. *See* 47 C.F.R. § 2.803.

In conclusion, Medtronic respectfully requests that the Commission reconsider its experimental license grant to Biotronik.

Respectfully submitted,

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January 2, 2003

Biotronik has explained, "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." Accordingly, Medtronic requests that the Commission make public Biotronik's entire experimental license application in November 2004.

[26] As the expected battery life for the devices exceeds the experimental period, Biotronik's equipment could impact MICS-compliant equipment well beyond two years. *See* note 2, *supra*.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on the date printed below, the preceding document was delivered by First Class U.S. mail to the persons listed below.

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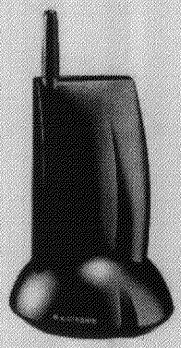
EXHIBIT 1

TO

PETITION FOR RECONSIDERATION

BIOTRONIK implants send messages straight from the heart. Conveniently. Automatically. Safely. With no patient intervention whatsoever – day and night. And your patient maintains complete mobility. A Cardio Report with all current, comprehensive data comes to you following an event or at any specific time or frequency that you decide.



BIOTRONIK's innovative Home Monitoring System:
A revolutionary approach to patient management.

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