Before the
Federal Communications Commission
Washington, D.C. 20554

In the matter of	)	
	)	
Biotronik, Inc.	)	
Equipment Authorization for the Medical	)	FCC Identifier PG6BA0T
Implant Communications Service	)	
	)	

MEMORANDUM OPINION AND ORDER

Adopted: February 12, 2003 **Released: February 25, 2003**

By the Commission:

I. INTRODUCTION

1. On April 23, 2001, the Commission's Office of Engineering and Technology (OET) granted an application for equipment authorization to Biotronik, Inc. (Biotronik) for its medical implant device, Philos DR-t.[1] This device is a low-power implanted transmitter that operates in conjunction with a medical pacemaker to facilitate data (non-voice) communication from the device to a doctor. The device is designed to communicate data in the event of certain changes in the patient's condition or through manual activation, and also at regular intervals for periodic monitoring of the patient's condition.

2. This grant was challenged by the manufacturer of another medical implant device, Medtronic, Inc. (Medtronic), and was modified by OET to disallow regular periodic transmissions.[2] Biotronik seeks reconsideration of that decision, arguing for restoration of the automatic transmission function by rule interpretation or by waiver. Medtronic seeks review of OET's determination to leave the equipment grant in place, albeit with certain restrictions, arguing that any operation of the device fails to comply with our rules. For the reasons stated below, we deny Biotronik's petition for reconsideration or waiver and deny Medtronic's application for review.

II. BACKGROUND

3. The Commission initiated the Medical Implant Communications Service (MICS) in 1999,[3] in response to a petition for rule making by Medtronic to permit use of a mobile radio device, implanted in a patient, for transmitting data in support of the diagnostic and/or therapeutic functions associated with an

[1] FCC ID: PG6BAOT.

[2] Letter to David E. Hilliard (Medtronic) and Mark Johnson (Biotronik) from Bruce A. Franca, Deputy Chief, Office of Engineering and Technology, FCC, March 28, 2002 (OET Letter).

[3] *Report and Order* in WT Docket No. 99-66 ("*MICS Order*"), 14 FCC Rcd 21,040 (1999).

implanted medical device.[4] This technology represented a significant advancement in communications with implanted medical devices in a manner that would be far more efficient, useful and safe than current systems.[5] The Commission determined that the 402–405 MHz band was particularly well suited for this service, due to the signal propagation characteristics in the human body, the relative dearth of other users of the band, the compatibility of a MICS service with the incumbent users of the band, and its use internationally for this purpose.[6]

4. In order to allow use of this newly-developed, life-saving medical technology without harming other users of the frequency band, MICS was provided a secondary allocation. At the time of this decision, the 402-405 MHz band was primarily allocated to Federal Government uses, including Meteorological Aids Service (Metaids), the Meteorological Satellite Service, and the Earth Exploration Satellite Service.[7] We adopted technical rules specifically designed to protect these incumbent Federal services and to ensure compatibility among multiple MICS devices and users.[8] These rules establish 10 channels of 300 kHz each for this service within the allotted bandwidth (47 C.F.R. § 95.628(c) (d)), provide for frequency sharing and cooperation in the selection and use of channels (47 C.F.R. § 95.1211), and establish specific guidelines for frequency monitoring prior to transmission by implant programmer/control transmitters (47 C.F.R. § 95.625(a)). We also provided that a MICS device could transmit without prior frequency monitoring, pursuant to a non-radio frequency actuation signal generated by a device external to the body (manual activation) (47 C.F.R. § 95.1209(b)), or in response to a medical implant event (47 C.F.R. §§ 95.628(b), 95.1209(b)). Given these protections, the National Telecommunications and Information Administration (NTIA), representing the incumbent Federal user entitled to exclusive use of this band, interposed no objection to this allocation.[9]

5. Under these newly adopted provisions, OET issued a Grant of Equipment Authorization to Biotronik to permit marketing and importation in the United States of its Philos DR-t model under the MICS rules. Whereas the Medtronic technology that served as the original instigation of this service and the basic model for our service rules is an external device that communicates with implanted equipment, the Biotronik device is an ultra-low power, non-broadcast transmitter that is implanted into the body with and operates in conjunction with a medical pacemaker. Its simpler function is to provide data (non-voice) communications to doctors regarding a patient's condition and its own performance. The device relays data for a doctor (typically to a data collection point) via a telephone (typically a cellular phone) that is in close proximity to the patient. As submitted to the Commission, the device could be activated manually by the patient using a magnetic wand, by certain changes in the patient's condition, or automatically on a

[4] This technology not only permits the reporting of the condition of the patient and the implanted pacemaker or other device, but also permits the doctor to reset certain parameters of the pacemaker's operation without the need to retrieve the device from the patient's body and have the device provide data back to report the results of the adjustments. See *Notice of Proposed Rule Making* in WT Docket No. 99-66 ("*MICS Notice"*), 14 FCC Rcd 3659, 3660 (1999).

[5] *Id.,* at 3661.

[6] *MICS Order, supra* at 21,042 – 43.

[7] In this band, Metaids currently operates radiosondes, which are automatic transmitters, usually carried on an aircraft, free balloon, kite, or parachute, which transmit meteorological data during their journey through the atmosphere. (See 47 C.F.R. § 2.1.)

[8] *Id.* at 21,046.

[9] NTIA is responsible for managing the Government portion of the Table of Frequency Allocations. In bands shared between Federal and non-Federal Government services, the Commission and NTIA operate under a long-standing coordination agreement. *See NTIA Manual, Basic Coordination Arrangement Between IRAC and the FCC*, at p. 8-39.

schedule set by the doctor. These automatic/periodic transmissions are used to assist doctors in identifying trends in a patient's condition in order to refine medical diagnosis and treat the patient.

6. Medtronic filed a Petition for Reconsideration of the Grant of Equipment Authorization. Medtronic contended that the one-way, single-frequency design of the Biotronik device is at odds with the basic MICS requirement to "share" frequencies among MICS users, citing the "cooperation" provision of Section 95.1211 of our rules. Medtronic argued that only devices that are frequency agile and that monitor frequency use prior to transmission, as provided in Section 95.628(a) of our rules, comply with this requirement. Medtronic also contended that, even under the medical implant event exception of Section 95.628(b), our rules require a "communications session," and that this requirement implies a two-way communication with multiple messages. Finally, Medtronic asserted that operation of Biotronik's device would pose an interference risk to other medical communications devices.

7. OET granted Medtronic's Petition for Reconsideration in part. OET determined that the Biotronik transmitter was in compliance with our rules and regulations except for the automatic transmissions that it incorporated. It determined that periodic operations of the equipment is not within the letter of the Commission's rules and accordingly modified Biotronik's Equipment Authorization to eliminate the provision for automatic transmission.[10]

8. Biotronik filed the instant Petition for Reconsideration of the OET reconsideration decision that limits their authorization by prohibiting automatic transmissions from the implanted device.[11] Biotronik argues that the automatic transmission provision is consistent with the MICS rules and should be reinstated. Biotronik alternatively seeks a waiver[12] of the Commission's rules to allow for automatic monitoring of a patient's condition, claiming that the short duration of the transmissions and the limited power employed during these transmissions obviate the risk of interference to other communications service or other medical devices.[13] Biotronik submits several letters from the medical community attesting to the value of the Biotronik device as a medical tool for diagnosis of cardiac problems. Medtronic filed in opposition to Biotronik's petition and alternative waiver request, and also filed the instant Application for Review of the determination to permit the more limited authorization.[14] Medtronic continues to contend that the Philos DR-t, even as limited in OET's most recent decision, is not in conformance with the MICS rules.

III. DISCUSSION

Medtronic Application for Review

9. In its Application for Review seeking complete rejection of all aspects of the Philos DR-t, Medtronic contends that MICS was created with the intention that users be frequency agile, monitoring the band and conducting the equivalent of an electronic handshake prior to operation, even in situations involving a medical emergency. Medtronic cites Section 95.1211(b), which requires "cooperat[ion] in the selection and use of channels." It further elaborates that the MICS rules, at Section 95.628(a), lay out monitoring and transmission provisions designed to ensure that the limited MICS spectrum is shared

[10] OET Letter, *supra* at p. 3.

[11] "Biotronik, Inc. Petition for Reconsideration or Waiver," April 8, 2002

[12] *Id.*

[13] The Philos DR-t would typically transmit for less than one-half second per day, in the early morning hours.

[14] "Opposition of Medtronic, Inc.," April 23, 2002; "Application for Review," filed by Medtronic, Inc., April 8, 2002.

equitably among all users and that the potential of interference to other MICS devices be minimized. It contends that the MICS rules intend that transmissions occur between the medical implant transmitter and an external medical implant programmer/control transmitter, which would coordinate frequency usage. The Philos DR-t does not employ a programmer/control transmitter, but contains only a medical implant transmitter and thus is not capable of this coordination. This, according to Medtronic means the Biotronik device is more likely to cause interference to other MICS devices, and is not contemplated by the rules in any mode of operation. Medtornic elaborates on its earlier arguments by contending that all MICS devices must have these capabilities, even though certain rule sections provide exceptions to this mode of operation. Finally, Medtronic argues that the very low power output on which OET based its determination of the lack of interference potential causes its receivers to be overly susceptible to interference from others, thus inhibiting the use of other MICS systems and of Part 15 devices.

10. We find that most of these arguments were fully considered and all were properly disposed of by OET. While the Philos DR-t may not perform in the manner of devices contemplated by Medtronic when Medtronic instigated a rule making for MICS, that service was not authorized for the limited purpose of accommodating only Medtronic's product or those that closely mimic its design. Biotronik has designed an apparently simpler utilitarian device whose functions are more limited but also provide a valuable medical tool. This device is consistent with the purposes of that service and fully comports with our rules as adopted when it is operated in the manner permitted by OET in its most recent decision. As OET has already pointed out, while a handshake/monitoring function is contemplated to minimize the interference potential of a MICS controller/transmitter that is not the only permissible mode of operation. The rules clearly contemplate a transmitter that is distinct and separate from its activation device, as here, and they state that *for an activation device that is a controller/transmitter*, certain protocols must be followed.[15] The Biotronik transmitter is not and does not include a controller/transmitter for its activation. Sections 95.628(b) and 95.1209(b) of our rules provide an exception to the monitoring requirement for transmissions that are initiated by a "medical implant event" (47 C.F.R. §§ 95.628(b), 95.1209(b)), and manual activation of a transmitter is not restricted by the transmission protocols governing activation by a controller/transmitter (47 C.F.R. § 95.1209(b)). In the case of a device such as the Philos DR-t that would operate only under the exceptions, as limited by OET's subject decision, it would be unnecessarily onerous for the Commission, as urged by Medtronic, to require a device to include a capability that would not be utilized - in this case a monitoring/handshake function - and we will not interpret our rules in such a manner.[16]

11. Medtronic also reiterates its earlier argument that the Commission based its MICS decision and rules on International Telecommunications Union (ITU) recommendations for such a service, and that OET failed to adequately consider the ITU recommendations that support its position. We find that OET was correct in discounting this argument. The ITU recommendation for MICS in this band provided additional impetus for this Commission to make a domestic MICS allocation at these frequencies, and provided guidance for appropriate operational parameters for controller/transmitters. However, as correctly observed by OET, the rules adopted do not mimic the provisions of the ITU recommendation, and we have distinguished between an implanted transmitter and its actuation device. Accordingly, we affirm OET's decision to authorize the Philos DR-t to operate manually and in the case of a medical implant event.

[15] "…no medical implant *transmitter* shall transmit except in response to a … medical implant programmer *control transmitter* or a non-radio frequency actuation signal …." (emphasis added) 47 C.F.R. § 95.1209(b).

[16] Medtronic's citation of the Wireless Telecommunications Bureau website discussion of MICS is unavailing. While website information is intended to provide useful information to persons outside the Commission, it does not have binding authority. (We note that the website information has been modified recently to better reflect Commission decisions in this area.)

Biotronik Petition for Reconsideration.

12. In its Petition for Reconsideration, Biotronik argues that the "scheduled event" that was disallowed in OET's decision, is a medical implant event as contemplated by the exemption of Section 95.628(b), even though the transmission is programmed to occur on a regular schedule. The rules define a medical implant event as an event recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from the medical implant transmitter in order to protect the safety or well–being of the person in whom the medical implant transmitter has been implanted. (47 C.F.R. App. 1 to subpart E of Part 95.) Biotronik insists that OET misunderstood the nature of the information included in the device's transmissions, asserting that the Philos DR-t transmissions include critical information regarding a patient's condition and reaction to pacemaker settings. According to Biotronik, the physician makes the determination as to a selected time and interval for the transmissions that are deemed medically necessary to assess the patient's medical condition and the proper operation or setting for a pacemaker. The physician or other qualified medical personnel programs (and can reprogram) the pacemaker to alter its function and to set the time interval for the Philos DR-t transmissions. Biotronik argues that only by reading this data and seeing trends can the physician appropriately observe the patient and intervene as needed.

13. Several physicians and health care facilities filed comments in support of Biotronik's petition. They contend that allowing doctors to collect cardiac data that is automatically transmitted at regular intervals is essential to observing patients' changing condition on a semi-real-time basis, and is invaluable as a diagnostic tool. They assert that never before have pacemakers been capable of automatically transmitting diagnostic cardiac data on a scheduled basis with such frequency and resolution. They contend that OET's reconsideration decision[17] was not consistent with the rule making and they seek to have the Commission grant Biotronik's petition for reconsideration and allow for these automatic transmissions on the basis that they are medically necessary and desirable for the purpose of patient care.

14. Medtronic counters that in establishing MICS, the Commission intended for MICS to be broadly applicable and intended to accommodate large numbers and numerous types of implantable therapies from many manufacturers. Accordingly, it argues, the Commission intended to provide a flexible framework, such that these devices could self-manage spectrum use, so as to facilitate sharing of the band, through electronic coordination, to avoid interference and without placing a burden on health care professionals.

15. While Medtronic's arguments here essentially echo those it raises in its Application for Review, discussed above, they are more compelling in the context of regular, preprogrammed transmissions. While OET may not have been fully apprised of the therapeutic functions of the regular monitoring transmissions when it made its subject decision, its technical analysis was correct. Channel scanning to avoid interference given and received was a key issue in our negotiations with the NTIA, and we clearly contemplated a two-way electronic handshake to occur before most automatic transmissions. We provided, with NTIA assent, exceptions for urgent situations and those individually controlled by manual operation. There is a difference between occasional transmissions instigated by an emergency situation or a change in a patient's condition recognized by the device or by the patient, and periodic transmissions that can be accommodated less urgently and in a way as to avoid conflict with other signals. To interpret the "medical implant event" exception as urged by Biotronik, to permit regular and potentially frequent transmissions with no specific instigation, would effectively eviscerate the protective provisions of the rules, and we cannot interpret our rules such that they have no effect. Accordingly, we

[17] OET Letter, *supra*.

affirm OET's decision that preprogrammed, regularly scheduled transmissions on a single channel without prior frequency monitoring, do not comport with the rules established for MICS.[18]

Biotronik Petition for Waiver.

16. Biotronik alternatively asks that if its device's preprogrammed periodic transmission function is not found in compliance with our MICS rules, it be granted a waiver of those rules to permit such monitoring/diagnostic operations by the device as originally submitted to the Commission for approval. Biotronik argues that the interference potential of such operations is *de minimis*, due to the very low power and short duration of the transmissions, and that only one channel is impacted. It states that the level of emissions are well below the allowable MICS level and are no more than we allow for computers and other digital devices, and are thus within limits the Commission has determined in the past to be relatively risk free of causing interference. It contends that a waiver would serve the underlying purpose of the rules by making diagnostic and therapeutic benefits available to the public while avoiding interference, and thus can and should be granted, citing *WAIT Radio*.[19]

17. Medtronic opposes this argument, contending that Biotronik has not met the burden for a waiver of our rules by failing to demonstrate a need for a waiver. Medtronic argues that Biotronik should not be allowed to circumvent the rules by using a waiver; that the device may be used in a variety of venues and as such may cause interference; and that granting the waiver would encourage other similar waiver requests.

18. We deny Biotronik's waiver request. While Biotronik argues that a waiver would not undercut the interests served by the rules, it has not even attempted to demonstrate that there is a hardship or burden in complying with them, or that a compliant device could not just as effectively serve patient needs.[20] We also note that while the interference potential from the Philos DR-t appears to be *de minimis*, as already recognized by OET, there appears to be a potential for interference to the device,[21] which could unreasonably impact other users of this band. Additionally, this spectrum is primarily allocated for Federal use (Metaids) and we give considerable deference to the NTIA in determining its potential impact on Federal use. Indeed, NTIA played a significant role in setting the service rules. In this case, NTIA does not agree that a waiver of the rules is appropriate for the Philos DR-t as presently formatted.[22]

IV. ORDERING CLAUSES

19. Accordingly, IT IS ORDERED that, pursuant to Sections 1, 4(i) and 4 (j) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154(i), 154 (j), the Application for Review filed by Medtronic is DENIED.

[18] Philos Dr-t devices that have already been implanted in patients are grandfathered, and can continue to be operated as originally configured and approved.

[19] *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C.Cir. 1969); *cert. denied* 409 U.S. 1027 (1972).

[20] See *Northeast Cellular v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir., 1990).

[21] OET Letter at 2.

[22] *See* Letter from Frederick R. Wentland to Edmond J. Thomas, November 5, 2002.

20. IT IS FURTHER ORDERED that, pursuant to Sections 1, 4(i) and 4 (j) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154(i), 154 (j), the Petition for Reconsideration or Waiver filed by Biotronik is DENIED.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary