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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

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Federal Communications Commission
Office of Secretary

In the Matter of)
)
Amendment of Parts 2 and 95 of the)
Commissions' Rules to Establish The) RM No. 11271
Medical Data Service at 401-402 and)
405-406 MHz)

ORIGINAL

COMMENT OF BIOTRONIK, INC.

Biotronik, Inc. ("Biotronik"), by its attorneys, hereby comments on the above-captioned Petition for Rulemaking ("Petition").

The best course of action would be for FCC to proceed with a rulemaking proceeding and to consider permanent changes in the present Medical Implant Communications Service ("MICS") regime to accommodate a wider range of devices that may operate on MICS frequencies.

Biotronik opposes any change to the rules that would create a separate service for low-power, low duty cycle medical implant devices and that would place this service on newly allocated spectrum. Such rule changes would be disruptive and unnecessary, and thus contrary to the public interest.

INTRODUCTION

Biotronik manufactures cardiac implant devices that transmit operational, diagnostic and therapeutic information to healthcare professionals via the public switched telephone network, both wireline and wireless. Biotronik's remote monitoring technology allows diagnostic and trend data, and other medically valuable information, of cardiac patients to be transmitted instantaneously from these implants at any time from almost anywhere in the United States. Previously, this type of data only could be

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collected infrequently during office visits by the implant patient to his or her physician once every six months or annually.

Biotronik's current line of cardiac implant devices that operate on MICS includes the Philos DR-T and Philos II DR-T pacemaker, as well as the Belos VR-T, Belos DR-T and Cardiac Airbag-T implantable cardioverter defibrillators. Biotronik's devices offer three modes of transmission. The Commission determined that two of the modes of transmission, activation upon a cardiac event or other change in a patient's condition and manual activation by the patient, comply with its rules. Biotronik obtained a waiver for the third mode of transmission, periodic scheduled emissions. Specifically, in February 2004, the Commission granted Biotronik a three-year waiver for certain of its devices to emit periodic scheduled transmissions without following the listen-before-transmit protocol.¹ In granting the waiver, the Commission recognized that it may need to reconsider the MICS rules in the future to more widely accommodate medical implant devices, an action Biotronik strongly supports.²

DISCUSSION

The Petition seeks to create a new Medical Data Service ("MEDS") for non-time sensitive medical monitoring via implanted or body worn external sensors.³ The Petition also seeks to allocate additional spectrum on the MICS sidebands (401-402 and 405-406 MHz) for MEDS transmissions as well as certain MICS transmissions.⁴ MICS transmissions that do not employ listen-before-transmit technology would be limited to the MEDS bands at ultra low power levels and low duty cycles of no more than 250 nanowatts EIRP and 3.6 seconds of total transmission time per hour.⁵ Medtronic

¹ See *In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 19 FCC Rcd 4208 (2004) ("Biotronik Waiver").

² Biotronik Waiver at 4214.

³ Petition at 2-3.

⁴ Petition at 6 n.9.

⁵ Petition at 11.

believes that the principal virtue of such a new service would be to permit lower cost medical devices and reduce the risk of interference to implanted MICS devices that are transmitting time-sensitive, life-critical medical data.⁶

The creation of a Medical Data Service separate from MICS is unwarranted. The Commission established the MICS service for “diagnostic and/or therapeutic functions associated with implanted medical devices to enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum.”⁷ While Biotronik agrees that the MICS rules should be changed, it believes the rules should be changed to accommodate more widely devices that may operate in the current MICS spectrum allocation, including devices that do not meet the present listen-before-transmit requirements. Biotronik also would support allowing a duty cycle that does not exceed 0.1% **in the current MICS band** for additional flexibility in serving the public need for medical implants.

I. BIOTRONIK OPPOSES ANY RULE CHANGE THAT WOULD RESTRICT CURRENT USE OF THE MICS SPECTRUM.

The Petition’s suggested segregation of medical implant devices by allowable use and listen-before-transmit ability is unnecessary and would be disruptive. The public interest would be better served by maximizing flexibility of the current MICS band through relaxation of the listen-before-transmit requirements.

A. The Proposed Limitations on Unidirectional Devices Are Unnecessary and Serve Only to Deny Patients Use of Highly Effective Medical Devices.

The Petition proposes requiring MICS devices that do not use listen-before-transmit technology to move to a new spectrum allocation in the MICS sidebands and to operate at low power and duty cycle levels. The Petition provides no sound reason for forcing such devices to move to new spectrum, as there is no indication that the

⁶ See Petition at 3-6.

⁷ Biotronik Waiver at 4208-09.

current MICS allocation suffers from interference caused by any devices. Rather, this rule change would limit the full range of medical implant devices that could be made available to the public.

B. The Proposed Change in the Allowed Use of MICS is Inconsistent with the Purpose of the Rules.

Biotronik opposes a change in the allowed use of the MICS band from “life sustaining” to “time sensitive, life critical” data. First, this is contrary to the Commission’s intended use of the spectrum, and was not contemplated by the Commission in its initial rulemaking. Second, the Petition does not provide any support that this rule change is necessary. MICS devices are secondary users of this frequency and, consistent with previous FCC rulings, medical devices that utilize the MICS band must not rely on the band for life-critical medical data. In fact, any medical device that incorporates a MICS communication must have risk mitigations in place to prevent possible loss of communication from compromising patient safety.

II. THERE IS NO NEED TO ALLOCATE ADDITIONAL SPECTRUM FOR MEDICAL IMPLANT DEVICES, AND BIOTRONIK OPPOSES ANY RULE CHANGE THAT WOULD REQUIRE MEDICAL IMPLANT DEVICES TO MOVE OUTSIDE THE EXISTING BAND.

Biotronik opposes the creation of a separate MEDS frequency allocation. Biotronik believes that any communication with implanted devices should remain exclusively within the already allocated MICS band. Considering that the MICS band was created specifically for this purpose and does not suffer from interference problems, it is unnecessary to create additional bandwidth for this purpose. Moreover, devices that do not use listen-before-transmit technology can co-exist with other MICS devices and should not be relegated to sidebands with stringent low power and low duty cycle requirements. Even Medtronic recognizes that devices that operate with low duty cycles can co-exist successfully with devices that employ listen-before-transmit technology.⁸

⁸ Petition at 2, 9 and 11.

A. Additional Spectrum Is Not Needed.

Biotronik opposes allocation of additional spectrum. Such allocation is unnecessary, as the present allocation of MICS spectrum is not heavily used and additional bandwidth is not necessary at this time for medical applications. As well, additional bandwidth for communication between two or more external or patient worn medical devices is not justified. There already are a number of short-range communication technologies that can be used for communications between external devices.

Additionally, FCC rejected Medtronic's claims, including its submitted studies, that the Biotronik devices would cause interference if they did not use listen-before-transmit technology.⁹ The Petition does not present any new information to indicate that the current MICS spectrum allocation cannot be used without interference, and does not justify allocation of new spectrum.

B. Additional Spectrum Would Be At Odds With International Spectrum Allocations.

Biotronik's devices, like other MICS devices, operate both in the United States and internationally. The proposed additional spectrum is not allocated to medical device use internationally, and thus could not be used by devices outside of the United States. Doing so would make it difficult for patients to travel abroad. This plan also would cause difficulty for device manufacturers to develop and manage two systems, one to function in the United States and one to function elsewhere in the world. FCC should maintain international harmonization by not changing the MICS spectrum allocation.¹⁰

⁹ Biotronik Waiver at 4212.

¹⁰ Although proposals for adding medical implant spectrum sidebands have been made internationally, to date none have been granted and none may ever be granted.

CONCLUSION

Biotronik opposes the creation of a MEDS allocation and the proposed segregation of certain MICS devices into the new spectrum. These rule changes are unnecessary and contrary to the public interest. FCC should proceed with a rulemaking proceeding and consider permanent changes in the present MICS regime to accommodate a wider range of devices that may operate on MICS frequencies. This approach also would be in line with proposed activity in other countries and regions, in particular Canada, Australia and Europe.

Respectfully submitted,

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September 23, 2005

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Comments of Biotronik, Inc., was sent by first-class mail, postage prepaid, this 23rd day of September, 2005, to the following:

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