Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of the	)	RM-11271
Commission's Rules to Establish the	)	
Medical Device Radio Communications	)	
Service at 401-402 and 405-406 MHz	)	

REPLY COMMENTS OF BOSTON SCIENTIFIC CORPORATION
CARDIAC RHYTHM MANAGEMENT

The Cardiac Rhythm Management business unit of Boston Scientific Corporation ("BSCCRM"), by its attorneys, respectfully submits its reply comments in the above-captioned proceeding. BSCCRM is a leading worldwide manufacturer of implantable cardiac devices such as implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy devices. BSCCRM is pleased that key members of the medical telemetry device industry have chosen to submit comments in response to the Notice of Proposed Rulemaking ("NPRM") and the Notice of Inquiry ("NOI").[1] The comments underscore the fact that the industry still has a long way to go to reach a consensus on how to reform the 400 MHz MICS band. BSCCRM believes that its proposals will achieve reforms without impeding the use of other medical telemetry applications. In addition, BSCCRM's proposal to include inductive telemetry in the MedRadio service under Part 95, a proposal that was not opposed, will enable more flexible use of the spectrum for medical implant telemetry.

[1] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz*, RM-11271, Notice of Proposed Rulemaking, Notice of Inquiry and Order (released July 18, 2006).

I. Introduction

As BSCCRM noted in its comments,[2] the MICS band has been underutilized in the six years since its allocation due primarily to the inadequate amount of spectrum allocated to the service and the restrictive nature of the current rules. Indeed, of the very few devices that have been brought to market, most require a waiver to operate. This is the unfortunate reality of MICS despite the fact that there is a burgeoning demand for implant telemetry.

BSCCRM's proposals are intended to preserve the new MedRadio[3] service as a viable infrastructure for health care applications that will take advantage of coming technological advances in medical telemetry. The other commenters in this proceeding share BSCCRM's view of the industry's future and agree that significant changes are needed. The question that remains is how to foster growth and development of the implant telemetry field in the most efficient and productive manner. BSCCRM believes that its proposals will satisfy the needs of industry and patients in the most effective manner and without prejudicing other users of the 400 MHz band.

II. Inclusion of Inductive Telemetry Devices Operating Below 1 MHz in MedRadio

BSCCRM proposes use of the 90-110 kHz band under MedRadio for inductive medical telemetry on a "licensed-by-rule" basis. As BSCCRM has explained, this approach is appropriate because of the virtually non-existent possibility of any interference from, or to, implants operating at current inductive power levels.[4] None of the commenters opposed this proposal. Partners HealthCare System, Inc. ("Partners"), explaining its support for the BSCCRM proposal, stated: "Given these devices are operating at low power and not in the vicinity of any radionavigation operations, it is difficult to see why there would be a reason to deny [BSCCRM's] proposal." Partners

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[2] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz*, RM-11271, Comments of BSCCRM (submitted October 31, 2006) ("BSCCRM Comments").

[3] BSCCRM uses the term "MedRadio" to refer to the entire allocation of Part 95 spectrum for medical devices proposed by the Commission.

[4] BSCCRM Comments at 6.

also noted that "the risk of interference is not from the very low-power medical device to the higher-power radionavigation systems, but vice-versa."[5]

BSCCRM also takes notice of the comments filed by Dr. Richard Mellish on behalf of the Medicines and Healthcare Products Regulatory Agency in the United Kingdom (the "Agency"). In his comments, Dr. Mellish stated that the Agency does not believe that very short range inductive coupling should be considered radio communication and that such operations should be permitted in any band and with any bandwidth suitable for medical purposes, as long as the emissions are within limits for incidental emissions.

BSCCRM has advocated this position for quite some time due not only to the low risk of interference but also to harmonize US regulations with those in Canada and Europe. BSCCRM notes, however, that the Commission has affirmatively determined that inductive communications devices are, in fact, intentional radiators subject to regulation.[6] Allowing a more flexible regulatory treatment for inductive devices by permitting them to operate on a "licensed-by-rule" basis similar to the MICS regime would be a middle ground that would be constructive and expedient, as it would enable physicians to select from a wider array of telemetry technologies for providing patient care.

III. Need for Additional Spectrum for Medical Devices

BSCCRM has proposed increasing the contiguous spectrum allocated for medical devices by a minimum of 12 MHz, thus creating the 401-416 MHz band for MedRadio.[7] Expanded device memory, made possible with technologies now coming to market, will require increased spectrum and channel bandwidths to speed the process of uploading patient data for analysis and treatment. Increased spectrum will also be necessary to

[5] Partners Comments at 9. As BSCCRM explained in its recent waiver petition, the risk of interference from radionavigation systems to medical devices is also virtually nonexistent. Among other reasons, it is highly unlikely that an RF signal from a radionavigation system would create an inductive signal capable of being detected by a medical device designed for encrypted localized inductive telemetry. *In the Matter of Boston Scientific Corporation Petition for a Limited Waiver of Section 15.205 of the Commission's Rules*, ET Docket No. 05-331, Petition for Waiver (dated June 6, 2006) at 10-11.
[6] 47 C.F.R. § 15.3(o).
[7] BSCCRM Comments at 7.

accommodate multiple independent telemetry sessions among co-located patients without causing interference.

Many commenters agree there should be an allocation of additional spectrum for medical devices, citing the needs of technologies currently in development. Even Medtronic, Inc. ("Medtronic"), which proposes the addition of only 2 MHz to the current allocation, believes that the Commission should identify additional bands to support future uses of medical telemetry.[8] The unresolved issue, however, is precisely how much spectrum should be allocated, and where.

The Alfred Mann Foundation ("AMF") stated in its comments that at least 5 MHz of new spectrum is required to support the need of the wireless implanted system it is developing to permit transmission of data at multiple sites without inordinate loss of battery life. Arguing that no suitable spectrum is currently available for wireless wideband medical devices, AMF has identified the 413-419 MHz, 426-432 MHz, 438-444 MHz and 451-457 MHz bands as possibly suitable to support operation of wideband medical implant devices on a secondary basis.[9] Similarly, GE Healthcare ("GEHC") believes that at least 5-10 MHz of spectrum is required to support the operation of a wireless "body sensor network" ("BSN") it is developing.[10] Like AMF, GEHC argues that no current spectrum is suitable for this application and plans to provide the Commission with its analysis of bands for potential BSN designation in the near future.[11]

While the details of, and bases for, commenters' proposals differ, there is uniform agreement that additional spectrum is desperately needed to accommodate new designs and developments in the medical arena. BSCCRM submits that its proposal to allocate an additional 12 MHz of spectrum offers the most effective solution for these voiced concerns, providing for a contiguous band of spectrum that can support the operations of multiple new technologies. More importantly, expanding the new MedRadio band in this manner will not impact the primary users of the 401-416 MHz band.[12]

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[8] Medtronic Comments at 17-19. Medtronic also believes that continuous spectrum will allow maximum efficiency of the design and operations of "body-area networks" ("BANs") that use both implanted MICS devices and body-worn medical devices that would operate in the Wing Bands. *Id*. at 6.
[9] AMF Comments at 9-12.
[10] GEHC Comments at 10.
[11] *Id*. at 14.
[12] BSCCRM Comments at 7.

IV. Maintaining 300 kHz as Permitted Bandwidth

Limiting the use of implants to 100 kHz channels, regardless of the location in the spectrum, runs counter to all of the trends in implant technologies. As BSCCRM explained in its comments, demand for additional communications channels is driven by a variety of factors, including increasing affordable device memory and the development of new diagnostic uses for implantable medical devices generally.[13] To conserve battery power, implants inherently need to transmit large quantities of patient data quickly, which cannot be done in 100 kHz channels. Therefore, BSCCRM proposes that conventional fixed frequency implants be permitted to transmit in 300 kHz channels as is presently the case and, even where necessary, be allowed to aggregate up to five adjacent 300 kHz channels for wideband communications.[14]

Biotronik, Inc. ("Biotronik") and DexCom, Inc. ("DexCom") share BSCCRM's views that the MICS spectrum should not be sub-divided for specialized operations at the cost of hampering wideband communications. Both oppose segregating the so-called "Wing Bands" from the rest of MedRadio based on device-specific operating characteristics, and generally oppose the imposition of different operating requirements for these bands.[15] BSCCRM agrees with Biotronik and DexCom that the operation of devices already in existence and of those currently under development are best supported by contiguous bands of spectrum with uniform operating standards. Like BSCCRM, AMI Semiconductor, Inc. ("AMIS") proposes permitting 300 kHz bandwidth across the entire MICS spectrum to minimize confusion, device complexity and patient costs.[16]

Medtronic argues in its comments that lowering the maximum bandwidth to 100 kHz in the Wing Bands will result in having at least 20 communications channels available and will preserve channel availability in the event a METAIDS radiosonde drifts into a Wing Band.[17] Medtronic does not explain, however, why this presents any more interference potential than if a radiosonde were to drift into the core 402-405 MHz

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[13] *Id*. at 8.
[14] *Id*. at 9.
[15] Biotronik Comments at 3-8; DexCom Comments at 3.
[16] AMIS Comments at 2.
[17] Medtronic Comments at 10.

band. Having a contiguous band for MedRadio from 401-416 MHz, as BSCCRM proposes, would largely mitigate the possible interference effects of such an occurrence. Moreover, if the use of alternative interference avoidance techniques such as spread spectrum frequency hopping suggested by BSCCRM is permitted,[18] these interference concerns can be avoided almost entirely without sacrificing the much needed flexibility of broadband communications.

V. Increase of Permitted Power Levels

BSCCRM proposes an increase in power from -16 dBm to 0 dBm EIRP for conventional fixed frequency MICS transmitters and to +7 dBm EIRP for frequency hopping transmitters to allow implants to communicate over greater distances, for example, to clear the sterile field in operating theaters and to allow for remote monitoring of multiple patients in congested facilities.[19] BSCCRM maintains that the medical telemetry technologies under development by other commenters, particularly for remote monitoring, will also benefit from an increase in permitted power levels.

DexCom opposes any imposition of more stringent power levels in the Wing Bands, arguing that its current short-term sensor ("STS") transmitter as well as other devices that use miniature transmitters and receivers will have difficulty operating at 250 nW EIRP. This power level, DexCom states, would lower the useful operating range of its STS device to less than two feet, rendering it unusable for patient monitoring. At the 25 mW level permitted under current rules, the reliable range of its device is, according to DexCom, only five feet. Although this seems to be only a slight improvement in range, this distance allows patients to lie on a sensor while asleep.[20] BSCCRM believes that even a five-foot "tether," available with the present power level, is too restrictive for patients who need to conduct normal activities without fear of compromising the operation of their devices.

BSCCRM has also proposed that the Commission amend the MICS rules to allow 16 dB more power to account for the power loss that occurs in the uplink from an

[18] BSCCRM Comments at 11-12.
[19] *Id*. at 10.
[20] DexCom Comments at 3-4.

external device to an implant due to tissue absorption and antenna loss.[21] Medtronic similarly recognizes the imbalance in the current MICS rules between the computation of power from implants and external devices and similarly proposes that the Commission allow a 4 dB correction factor for the measured field strength of body-worn transmitters to allow for tissue absorption.[22] Clearly, any power limitation that properly takes into account tissue absorption must be permitted for both implants and external transmitters.

VI. Allowance of Alternative Interference Avoidance Techniques

BSCCRM has explained that restricting the interference avoidance protocol in the MICS band to one particular implementation reduces the choices available to manufacturers to implement other reliable communications links. For this reason, BSCCRM submits that the current listen-before-talk ("LBT") rules should not be mandated.[23] Rather, BSCCRM believes there should be no required frequency scan, or LBT, for implants which feature alternative interference avoidance techniques such as spread spectrum frequency hopping.[24]

Generally, parties that commented on MICS interference avoidance requirements either believe that such requirements are unnecessary or support the notion that additional methods should be permitted without mandating any particular protocol.[25] Biotronik and DexCom, for example, advocate a variety of methods for interference avoidance, including adaptive frequency agility ("AFA"), cycle redundancy checks with error correction, retransmission of "missed" packets and failsafe operation modes.[26] As BSCCRM, Biotronik and AMIS argue, the current LBT requirements burden devices with increased complexity, resulting in excessive delays in data transfers that lead to increased drain on battery power and shortened life cycles for all telemetry devices.[27] In addition, Biotronik notes that the advantages of employing low-power, low-duty cycle

[21] BSCCRM Comments at 10-11.
[22] Medtronic Comments at 10-11.
[23] BSCCRM Comments at 11.
[24] *Id*.
[25] GEHC proposes the definition of "spectrum sharing etiquette" to prioritize the relative "quality of service" among devices. GEHC Comments at 16. Partners proposes the development of standards to minimize harmful interference, with existing devices "grandfathered" into new rules. Partners Comments at 5-6.
[26] Biotronik Comments at 6; DexCom Comments at 5.
[27] BSCCRM Comments at 11, Biotronik Comments at 10; AMIS Comments at 2 and 4.

("LPLDC") designs without LBT, which conforms to international usage, enables the use of lower power consumption and the ability to use less complex designs.[28] Finally, AMIS notes the constraints imposed by LBT on the technical capabilities of MICS band radios and suggests that LBT be considered only for high duty cycle transmissions.[29]

In contrast, Medtronic argues that LBT and AFA should continue to be required for the core 402-405 MHz of the band, citing the Commission's comment that there is no reason to "upset" the rules for the core bands, as the industry is still in its "nascent stages."[30] However, the comments filed in this proceeding disagree with Medtronic's proposals and support BSCCRM's view that the industry is in its nascent stages because of costly and power-consuming requirements such as LBT. Advancements in medical telemetry will require a flexible regulatory scheme that promotes technical innovation without adding layers of unnecessary regulation.

Biotronik also proposes allowing the operation of LPLDC devices within the 401-406 MHz band without LBT. However, Biotronik, AMIS and St. Jude Medical would limit this operation to a single "beacon" channel in the middle of the core 402-405 MHz band. These commenters argue that this "beacon" channel will reduce device complexity and provide significant power savings without posing a threat of interference to other users of the surrounding bands.[31] While BSCCRM generally supports modifications to the Commission's operating rules that would promote these goals, a universal beaconing scheme would simply introduce unnecessary complexity into the regulatory regime already in place. BSCCRM opposes the use of a beacon channel in the middle of the band as an intrusion in contiguous spectrum which, BSCCRM has explained, is essential to the infrastructure needed for high speed telemetry devices.

In summary, given the variety of "off the shelf" interference avoidance techniques on the market today, mandating a particular interference protocol for medical telemetry is not in the public interest. Moreover, as the comments filed in this proceeding demonstrate, allowing the use of other interference avoidance methods will promote technological innovation and improve the operation and efficiency of existing medical telemetry devices.

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[28] Biotronik Comments at 10-11.
[29] AMIS Comments at 2.
[30] Medtronic Comments at 6-7 (citing the NPRM at ¶ 24).
[31] Biotronik Comments at 9-10; AMIS Comments at 3; St. Jude Medical Comments at 1-2.

VII. Conclusion

The comments filed in this proceeding demonstrate agreement among most industry manufacturers that significant changes are needed to the current MICS allocation and operating rules. For the new MedRadio service to be the useful telemetry service envisioned by the Commission, it will require more power, more bandwidth and greater technical flexibility when it comes to interference avoidance. BSCCRM believes that its proposals support most, if not all, of the foreseeable medical implant telemetry applications under discussion today by: (1) allowing operation of inductive telemetry devices on a "licensed-by-rule" basis; (2) a greater allocation of spectrum that will support the new medical telemetry technologies; (3) providing adequate bandwidth to meet demands for increased device memory and expanded monitoring of patient health; (4) increasing permitted power levels to improve device reliability and patient monitoring; and (5) allowing manufacturers to choose the most effective interference avoidance techniques for their devices.

Respectfully submitted,

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December 4, 2006