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November 1, 2007

VIA ECFS AND E-MAIL

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

Re: Investigation of the Spectrum Requirements for Advanced Medical Technologies – ET Docket No. 06-135
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

Dear Mr. Knapp:

This letter responds to recent ex parte submissions in the above-referenced dockets from Transoma Medical and Biotronik, Inc. As explained below, the FCC should reject Transoma's proposal to permit medical testing in the 401-406 MHz MedRadio band with non-human (*i.e.*, animal) subjects. As Transoma itself recognizes, the types of monitoring and testing that it wants to conduct in the band can be supported in other spectrum. Given the nascent stage of medical device deployment in the MICS band, now is not the time to expand the types of allowable uses beyond what the rules currently permit – that is, RF devices that licensed health care providers use in the treatment of patients.

Next, Medtronic reiterates its opposition to allowing non-LBT operations in the core 402-405 MHz MICS band. Medtronic shows that the Biotronik interference analysis fails to characterize accurately the operation of LBT/AFA devices in the MICS band. Even so, the analysis still demonstrates that interference **will** occur. Such interference to medical communications can have serious consequences as commenting parties have noted.

The Commission Should Reject Transoma Medical's Request To Expand Allowable Uses In The Entire 401-406 MHz Band.

Transoma is seeking to open the 402-405 MHz core MICS band and proposed 401-402 and 405-406 MHz wing-band allocation for animal testing in "laboratory environment[s] for the purpose of discovery, development, and testing of pharmaceuticals, medical devices and surgical techniques." Transoma Medical Aug. 23, 2007 Ex Parte Letter in ET Docket Nos. 06-135, 05-213, 03-92, and RM-

11271; *see also* Transoma Medical Aug. 28, 2007, Ex Parte Letter in ET Docket No. 06-135. Medtronic believes that the FCC should maintain the current limitations in the MICS rules (and proposed rules for the wing-band allocation) requiring that this spectrum be used for the medical treatment of humans.[1]

When it promulgated the MICS rules, the Commission sought to define a band for use by patients with implantable medical devices, and in so doing, rejected opening the band to any and all types of communications somehow related to healthcare including use for laboratory testing with animals. As the Wireless Bureau explained earlier this year in rejecting Transoma's Request for Interpretation asking the FCC to allow this type of use under the MICS rules:

> The MICS rules clearly contemplate that MICS devices will be used solely for the medical treatment of individual patients by licensed health care providers. … Throughout the rulemaking proceeding establishing the MICS, … the service was repeatedly described as one intended to enhance the medical treatment of individual patients. In addition, we note that the rules expressly refer only to implantation of MICS devices in humans. Had the Commission intended to authorize other uses of MICS devices, such as to facilitate research and development by the pharmaceutical industry, we believe it would have done so expressly.

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[1] *Body-worn transmitter.* A MEDS **transmitter intended to be placed on or in very close proximity (i.e., 6 centimeters or less) to the human body** used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient. **…**

Medical implant device. Apparatus that is **placed inside the human body** for the purpose of performing diagnostic or therapeutic functions.

Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order **to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted**.

Medical implant programmer/control transmitter. A MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device.

Medical implant transmitter. A MICS or MEDS transmitter **that operates or is designed to operate within a human body** for the purpose of facilitating communications from a medical implant device.

See Appendix 1 to Subpart E to Part 95, "Glossary of Terms," *and see* MEDS Petition for Rulemaking, RM-11271 (July 15, 2005) (emphasis added).

Transoma Medical, Inc., Request for Interpretation of MICS Rules, *Order*, DA 07-801, ¶ 4 (WTB Feb. 22, 2007) (footnotes omitted).

The recent MedRadio NPRM further explained that: "The MICS service was anticipated to transmit data in support of the 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." Investigation of the Spectrum Requirements for Advanced Medical Technologies, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, ET Docket No. 06-135, 21 FCC Rcd 8164, 8167 ¶ 7 (2006) (emphasis added).

Contrary to Transoma's claim that its proposed use will be limited to certain areas, the operational locations listed in its August 28 Ex Parte filing are places where people with MICS implantable devices will be found, namely medical and pharmaceutical industry laboratories, and private, government and academic research laboratories. Additionally, the term "laboratory" – much like the term "clinic" – is so broad that it could include locations in countless office buildings, many residential settings, and healthcare facilities.

Significantly, as Transoma acknowledges, it can operate its RF systems in other bands. *See* Transoma Medical Sept. 28, 2007 Ex Parte Presentation at 13 ("For lab animal telemetry systems that now need greater range and spectrum bandwidth, a higher frequency such as the 902-928 MHz ISM band might be a choice."). For these reasons, the Commission should reject Transoma's calls to expand the allowable uses in the 401-406 MHz MedRadio band.

Biotronik's Interference Analysis Is Flawed.

Biotronik recently published a paper analyzing the probability of LP-LDC to LBT interference in the core MICS band. *See* Biotronik Sept. 27, 2007 Ex Parte Letter (attaching Brian Sutton, *et al.* Probability of Interference between LP-LDC and LBT MICS Implants in a Medical Care Facility, IEEE EMBS, Aug. 23-26, 2007). Despite Biotronik's claim that such interference is "virtually non-existent," the data presented in the paper show that interference will occur.

Moreover, the interference analysis contains flaws, indicating that the real-world interference may be substantially greater than Biotronik claims. In particular:

- Biotronik calculates a probability of collision between $n \geq 1$ LP-LDC transmissions and a single 100 ms LBT packet, which is unrepresentative of the real world. In clinical settings, the majority of LBT sessions will have durations well beyond 100 ms, increasing substantially the likelihood of a collision with LP-LDC transmissions.
  - In a physician's office, a MICS communications session can occupy a channel for 15 to 30 minutes.
  - Real-time EGM signals typically require 30 to 120 minutes per session (and often longer).
  - During left ventricular lead placements for cardiac resynchronization therapy, 2 hour implant procedures are typical but also have extended beyond 4 hours.
  - The Biotronik paper itself recognizes that LBT sessions "could last for several minutes," Paper at 6721, yet still used a 100 ms duration.

  Biotronik's calculations of the probability that LP-LDC transmissions will collide with a 100 ms LBT session does not accurately model real-world uses of MICS LBT communications systems.[2] With heavy channel use, the possibility for interference from non-LBT operations will increase.
- Biotronik improperly assumes a duty cycle limitation for LBT communications when no such restriction exists.
- The Biotronik paper incorrectly states that "the [LBT] protocol can consume a significant amount of power from the implant's battery." Paper at 6721. In fact, the clear channel assessment portion of the MICS LBT protocol has limited impact on implant power consumption because it is conducted by the external MICS programmer/controller, not the implant. Biotronik also fails to appreciate the remarkable advancements in MICS transceiver designs. Zarlink Semiconductor has proven that low-power frequency-agile, LBT-type MICS transceivers are achievable.

[2] Biotronik's discussion relating to "hidden node" does not consider the role of upper layer protocol (*i.e.*, above OSI Layer 1) in a two-way communications system. For instance, a manufacturer may choose to implement virtual carrier sense mechanisms similar to those employed by IEEE Std 802.11 to mitigate hidden node issues (*e.g.*, "Request to Send (RTS)" and "Clear to Send (CTS)" messages). The LBT scan duration also can be used to mitigate hidden node issues.

- Next, Biotronik claims that most regulatory agencies that have adopted MICS are considering allowing users to implement LBT *or* LP-LDC. *Id*. at 6721. In fact, the trend has been LBT only or LBT *and* LP-LDC. Even the European rules, on which Biotronik heavily leans, require that external programmer/controllers in the core band use LBT and only permit LP-LDC operations from the implantable medical device on one fixed frequency channel.

The Proposed LP-LDC Mode Of Operation Can Be Supported In The 401-402 & 405-406 MHz Wing Bands, And The FCC Should Require That Such Operations Currently In The Core MICS Band Pursuant To A Waiver Move To The Wing Bands Upon Their Authorization.

The power level, duty cycle, and bandwidth limits that have been proposed for the LP-LDC mode in the wing bands are more than sufficient for Biotronik's application.[3] Moreover, the wing bands were not available when the FCC granted waivers to permit such LP-LDC operations in the core 402-405 MHz band.

Any claim that these particular device applications need to be placed in the core MICS band because that band is quieter than the wing bands does not withstand scrutiny. In fact, the 403.5-403.8 MHz band identified by Biotronik is very close to the nominal center frequency of METAIDS radiosondes – the primary occupants of the 401-406 MHz band. *See* Reply Comments of Medtronic at 14 n.43, Amendment of Parts 2 and 95 of the Commission's Rules To Establish The Medical Data Service at 401-402 and 405-406 MHz, ET Docket No. 06-135, Dec. 4, 2006. Biotronik's device would be further away from METAIDS devices and thus suffer less interference were it to operate in the wing bands.

Notwithstanding the foregoing, should the FCC decide to permit LP-LDC operations in the core MICS band, it should go no further than permitting the limited type of ultra-low-power, low-duty-cycle operation that has been allowed in

[3] *See* Biotronik Grant of Equipment Authorization PG6CYLOS, noting an Output Power Level of 2.4 nanowatts EIRP and Emission Designator of 46K0F1D, which corresponds to a 46 kHz emission bandwidth. *See also* Biotronik Grant of Equipment Authorization PG6BA0T, noting an even lower Output Power Level of 1.2 nanowatts EIRP and the same Emission Designator of 46K0F1D and associated 46 kHz emission bandwidth. The proposed duty cycle of 0.1% for the LP-LDC mode in the wing bands is more than adequate for Biotronik's application, which uses a duty cycle of 0.01%.

Europe[4] and was proposed by St. Jude Medical and Zarlink Semiconductor in this proceeding.[5] Specifically, LP-LDC access in the core band should be limited to:

(1) spectrum between 403.5 and 403.8 MHz;

(2) transmissions from the implantable medical device only;

(3) 0.01 % maximum duty cycle (that is, no more than 360 milliseconds transmission time during any one-hour period);

(4) 100 nanowatts ERP transmit power;

(5) no more than 10 transmissions per hour with the total transmission time less than or equal to 360 milliseconds, and

(6) devices operating in the LP-LDC mode may not use the medical implant event exception.

Biotronik's proposed use of the 403.5 to 403.8 MHz "channel" as a beacon channel should be rejected because it contrary to the terms of the FCC's waiver and the European standard.

To conclude, Biotronik has acknowledged its device will cause interference to LBT systems. The probability of such interference, however, is an open question. Notwithstanding, the FCC must consider whether it is good public policy to permit an LP-LDC device in the core band that will interfere with LBT devices (*e.g.*, ultra-low-power implantable medical devices) transferring life-critical and time sensitive data especially where the LP-LDC device can operate in one of the wing bands just outside the core MICS band. The proposed rules for the wing bands fully

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[4] *See* ETSI EN 301 839-1 V1.2.1 (2007-04), European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods; *and* ETSI EN 301 839-2 V1.2.1 (2007-04), Harmonized European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive.

[5] *See* St. Jude Medical Comments (Oct. 27, 2006) at 1; Zarlink Semiconductor Comments at 2. Biotronik's analysis appears to be based on these parameters. *See* Paper at 6723 (Table I).

accommodate the operation of LP-LDC devices, such as Biotronik's, and would protect the MICS band from interference from such operations. Any device deployment delays due to minor technical revisions and medical approvals may be accommodated by permitting a transitional relief period.

Sincerely,

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cc: Geraldine Matise
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