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January 10, 2008

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: *Ex Parte* Presentation
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:

ETSI Standard Adopted. Medtronic is pleased to inform the Commission that CEPT recently approved the ETSI standard governing low-power medical data communications in the 401-402 MHz & 405-406 MHz bands.[1] In accordance with this action, Medtronic proposes revisions to two rule sections in its Petition for Rulemaking to Amend Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz, RM-11271, which it filed with the Commission on July 15, 2005 ("Petition for Rulemaking").

First, Medtronic proposes an amendment to the Listen Before Transmit ("LBT") threshold power level to align it with the related provision in the ETSI standard (i.e., Section 10.2) covering operations in the 401-402 and 405-406 MHz wing bands. Medtronic is proposing to add one sentence and an explanatory note to Rule Section 95.628(a)(3) as shown in the attachment to this letter. The amendment is needed to enable body worn and implantable devices providing the LBT and Adaptive Frequency Agility ("AFA") functionality because the antenna gain as well as body absorption and proximity effects significantly affect monitoring system sensitivity

[1] *See* Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods and Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive; Details of 'DEN/ERM-TG30-005-1' and 'DEN/ERM-TG30-005-2' Work Items are *available at* http://webapp.etsi.org/workprogram/Report_WorkItem.asp?WKI_ID=24721 and http://webapp.etsi.org/workProgram/Report_WorkItem.asp?WKI_ID=24722.

relative to that of an external programmer/control transmitter that typically transmits close to the maximum permitted power level.

Second, Medtronic proposes amending existing Rule Section 95.639(f) relating to maximum transmitter power so that the emissions limits for body worn devices at 401-402 and 405-406 MHz are measured using a human torso simulator similar to measurements of implant transmitter power currently in subsection (f) for core-band MICS operations at 402-405 MHz. Here, Medtronic proposes revising Section 95.639(f), as shown in the attachment, to align the maximum transmit power measurement approach for body-worn devices with the approach set forth in the ETSI standard, which does not include the 4 dB correction factor proposed in the Petition for Rulemaking.

Also, the recently approved ETSI standard governing medical data communications systems at 401-402 & 405-406 MHz requires these wing band systems to access a minimum of eighteen channels distributed across the band.[2] Similarly, as Medtronic previously informed the Commission, the ETSI standard governing core-band medical implant communications system operation at 402-405 MHz requires MICS systems to access a minimum of nine channels distributed across the core band.[3]

Reply to Biotronik and Transoma. Medtronic recognizes the recent submissions in the above-referenced dockets by Biotronik and Transoma Medical on November 29 and 30, 2007, respectively.

Biotronik. Medtronic appreciates Biotronik's clarification that its proposed "beacon channel" mode of operation would be an implant-initiated transmission exclusively. Medtronic opposed Biotronik's request to permit a beacon mode of operation based on the commonly understood use of the term *beacon*. A radio beacon commonly

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[2] *See* ETSI EN 302 537-1 V1.1.2 (2007-12) European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods, § 3.1 Definitions: Medical Data Service (MEDS) System Device. The ETSI standard also allows single-channel MEDS devices so long as they use the low-power, low-duty-cycle spectrum access mode.

[3] *See* Letter from David Hilliard, Counsel for Medtronic, to Julius Knapp, Chief of the FCC's Office of Engineering and Technology, Sept. 13, 2007, ET Docket No. 06-135 and RM-11271 at 3 citing ETSI EN 301 839-1 V1.1.1 (2002-06) § 3.1 Definitions – medical implant communications channel.

refers to an external transmitter that transmits a signal on a specified radio frequency for purposes of coordinating communications.

The problems Medtronic identified with the Biotronik interference analysis remain valid. Should the FCC, nonetheless, permit low-power, low-duty-cycle ("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 Europe[4] and was proposed by St. Jude Medical and Zarlink Semiconductor in this proceeding.[5] Specifically, LP-LDC access in the core band, which includes Biotronik's beacon mode of transmission, 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.

Transoma Medical. Given the nascent stages of product deployment in the core MICS band, Medtronic recommends that the Commission continue to allow Transoma Medical to operate MICS-compliant devices implanted in animals for purposes of laboratory testing pursuant to experimental authorization. In this way,

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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.

the FCC will be apprised of the areas in which the RF animal testing is being conducted while active implantable medical devices with MICS capability are deployed more widely. This is a very workable approach given the usage model and number of transceivers that Transoma has proposed for animal testing in the core band.

Sincerely,

David E. Hilliard

David E. Hilliard
John W. Kuzin

cc: Geraldine Matise
Bruce Romano
Mark Settle
Alan Stillwell
Gary Thayer
Jamison Prime

Att.

ATTACHMENT

§ 95.628 Spectrum Sharing Requirements for MICS and MEDS Transmitters**.**

. . .

(3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than 10logB(Hz) - 150 (dBm/Hz) + G(dBi) where B is the emission bandwidth of the MICS **or MEDS** ~~communication session~~ transmitter having the widest emission and G is the ~~medical implant programmer/control transmitter~~ monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively. **If the monitoring system of a medical implant transmitter or body-worn transmitter is used to select the channel, then the threshold power level requirement may be adjusted 1 dB higher for every 1 dB the EIRP of the transmitter is below the maximum permitted level of 25 microwatts EIRP.**

NOTE: By way of example, for a medical implant transmitter or body-worn transmitter with an EIRP 10 dB lower than the maximum permitted level of 25 microwatts, +10 dB may be added to the above equation, resulting in a threshold level of 10logB(Hz) – 150 (dBm/Hz) + G(dBi) + 10. This adjustment permits the monitoring system function in applications where antenna gain and body absorption or proximity effects significantly affect system sensitivity relative to conventional medical implant programmer/control transmitters. For a monitoring system integral to a medical implant transmitter or body-worn transmitter, the antenna gain (G) includes body absorption for implanted and body-worn devices, relative to an isotropic antenna.

§ 95.639 Maximum transmitter power.

* * *

(f) In the MICS **and MEDS** the following limits apply:

(1) The maximum EIRP for MICS **or MEDS** transmitter stations is 25 microwatts. The antenna associated with any MICS **or MEDS** transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance of any MICS **or MEDS** transmitter with the 25 microwatts EIRP limit**, or of any MEDS transmitter with the 250 nanowatt EIRP limit allowed under section 95.628(b),** may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts EIRP is 18.2 mV/meter when measured on an open area test site, or 9.1 mV/meter when measured on a test site equivalent to free space such as a fully anechoic test chamber. **The equivalent radiated field strength at 3 meters for 250 nanowatts EIRP is 1.82 mV/meter when measured on an open area test site, or 0.91 mV/meter when measured on a test site equivalent to free space such as a fully anechoic test chamber.** In either case, compliance is based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, instrumentation techniques set forth in ANSI C63.17-1998, Section 6.1.2.2.1 or Section 6.1.2.2.2 may be used in determining compliance with the above specifications.

(2) For a transmitter intended to be implanted in a human body **or a body-worn transmitter**, the following test fixture must be used to simulate operation of the **transmitter** ~~implant~~ under actual operating conditions. See § 95.605.

(i) For measurement purposes to determine compliance with emission limits, the radiating characteristics of an implant **or body-worn** transmitter placed in **or adjacent to** a test fixture should approximate those of an implant transmitter placed in a human body **or a body-worn transmitter placed on a human body.** An appropriate human torso simulator for testing medical implant **or body-worn** transmitters consists of a cylindrical Plexiglas container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. **The fixture contains the medical**

implant transmitter mounted on the inside of the human torso simulator or the body-worn transmitter mounted on the outside surface of the human torso simulator. The human torso simulator~~It~~ must be completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. The dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements will be made using the above specification at a nominal temperature of 20-25 deg C. Simple saline solutions do not meet the above criteria. A mounting grid for the implant inside the container must be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function in a fixed repeatable manner. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. **The body-worn transmitter must be positioned vertically on a mounting shelf that is centered on the exterior surface of the container along with any associated leads.** The above fixture shall be placed on a turntable such that the implant transmitter **or body worn transmitter** will be located at a nominal 1.5-meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

(ii) A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in "Bioelectromagnetics 8:29-36 (1987)".

(3) The power radiated in any 300 kHz bandwidth **from a MICS transmitter or in any 100 kHz bandwidth from a MEDS transmitter** shall not exceed 25 microwatts EIRP**, except in the case of a MEDS transmitter operating under the low-power, low duty cycle provision in section 95.628(b)**. See §§ 95.633(e) and **95.633(h)**.

[Subsection (j) to FCC Rule Section 95.639 proposed in the Petition for Rulemaking, which provided for a 4 dB correction factor, is no longer necessary given the revisions to (f) above.]