Wiley Rein LLP

1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wileyrein.com

David E. Hilliard
202.719.7058
dhilliard@wileyrein.com

John W. Kuzin
202.719.3506
jkuzin@wileyrein.com

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VIA ECFS

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

Re: *Ex Parte* Filing - 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:

Medtronic hereby responds to the recent *ex parte* submissions from St. Jude Medical in the above-referenced dockets.[1] St. Jude is asking the Commission to permit temporary operation in the core 402-405 MHz MICS band of body-worn devices connected percutaneously to an implanted medical device. St. Jude has proposed that such operation be limited to the following conditions:

(1) there must be a sound diagnostic and therapeutic justification for operating the transmitter external to the body;
(2) external RF operation is temporary and permitted solely to evaluate the efficacy of an implanted medical device and, following the temporary evaluation period, the external RF device will be replaced by a fully-implanted MICS compliant device;
(3) external device operation must comply with the existing Listen Before Talk ("LBT") and Adaptive Frequency Agility ("AFA") requirements;
(4) external device operation shall occur at an appropriate field strength limit to account for the lack of body absorption that affects implanted transmitters; and
(5) both the temporary external device and fully implanted device must otherwise meet the existing core MICS band rules.[2]

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[1] *See* St. Jude Medical *Ex Parte* Filing (July 17, 2008); Advanced Neuromodulation Systems, Inc., A St. Jude Medical Company, *Ex Parte* Notice (July 17, 2008).

[2] *See id.*

Medtronic applauds St. Jude Medical's recognition of the critical role that the MICS rules and associated LBT and AFA regulations are playing in the successful deployment of implantable medical devices in the 402-405 MHz band.[3] There can be no question that the recent growth of MICS band devices has been astounding. Medtronic MICS-compliant programmer/controllers are now fielded in cardiology centers throughout the U.S. and internationally. And, as of July 24, 2008, there are more than 132,000 Medtronic MICS implantable cardiac devices in operation worldwide.[4] Also, just last month, Zarlink Semiconductor announced that it had shipped more than 30,000 MICS-compliant transceiver chips to St. Jude Medical for use in its cardiac, neurological, and chronic pain relief implantable medical devices.[5] Maintaining the core band's self-regulating spectrum management capability is critical to the continued growth of implantable RF medical devices.

Based upon the proliferation of MICS band implantable medical devices, Medtronic believes that St. Jude Medical's temporary external application is better suited for the proposed 401-402 and 405-406 MHz wings bands.[6] The proposed rules for the wing bands explicitly permit external-to-external operation and up to 25 μW for devices performing LBT and AFA.

Nonetheless, should the Commission decide that St. Jude Medical's proposed MICS-band operation should be permitted, Medtronic believes that the following clarifications should be included in any revised rules:

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[3] Medtronic recognizes that Biotronik's pending request to permit ultra-low-power, low-duty-cycle operations by fully implanted devices at 403.5-403.8 MHz would be an exception.

[4] That is a 32% increase over the figure Medtronic provided in its April 9, 2008 ex parte filing, and it is more than three times the amount that Medtronic reported just one year ago. *See* Medtronic Ex Parte Presentation (July 26, 2007).

[5] *See* Zarlink Semiconductor Press Release, "Zarlink Radio Chip for In-Body Communications Shipping in Volume to Leading Medical Device Manufacturer"(July 18, 2008) *available at* http://www.zarlink.com/cps/rde/xchg/zarlink/hs/press_releases_15238.htm.

[6] In fact, St-Jude's proposed operation would be fully supported by the rules proposed for the wing bands. *See* 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 (2006).

(1) the external device must comply fully with the existing MICS rules, including the ability to function under the control of LBT and AFA throughout the core 402-405 MHz band;

(2) RF transmissions from the external device must cease following the efficacy evaluation period, which may not exceed 30 days; only an external device that is intended to be replaced by a fully implanted device may transmit in the core band; and

(3) the external device power level may not exceed 200 nW EIRP.[7]

Medtronic appreciates St. Jude's recognition that any such external device operation should be at an appropriate field strength limit, for these external devices will be occupying the same spectrum as ultra-low-power implanted devices currently operating at levels well below 100 nW EIRP.[8] External device operation at the maximum power level of 25 μW EIRP – even on a temporary basis – would impact the battery life and performance of the rapidly growing number of fully implanted devices, which are expected to operate reliably for up to a decade in many cases.

Sincerely,

David E. Hilliard

David E. Hilliard
John W. Kuzin

cc: Ira Keltz
Ron Repasi
Mark Settle
Gary Thayer
Geraldine Matise
Bruce Romano
Alan Stillwell

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[7] *See* FCC Equipment Authorization database for FCC ID: RIASJMRF (St. Jude Medical implantable medical device operates at less than 200 nW EIRP).

[8] Biotronik's implanted cardiac devices operate with less than 10 nW EIRP. *See* FCC Equipment Authorization database for FCC ID: PG6BELOS-T (operating at 8 nW EIRP); PG6BA0T (operating at 1.2 nW EIRP). Medtronic's MICS implants have a maximum EIRP of 50 to 60 nW. *See* FCC Equipment Authorization database for FCC ID: LF5MICSIMPLANT.