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November 20, 2008

VIA ECFS

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
445 12th Street, SW
Washington, DC 20554

**Re: *Ex parte* Notice: 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 Ms. Dortch:

On November 19, 2008, Robert L. Pettit and the undersigned of Wiley Rein LLP, as counsel to Medtronic Inc., met with Charles Mathias, Legal Advisor to Chairman Kevin Martin, to discuss the above-referenced proceedings. Medtronic encouraged the Commission to authorize the proposed MEDS wing bands at 401-402 and 405-406 MHz and to reaffirm the established Medical Implant Communications Service (“MICS”) rules at 402-405 MHz, as explained in the attached document entitled “MedRadio Rulemaking,” a copy of which was left with Mr. Mathias.

Medtronic also provided Mr. Mathias with a copy of the attached slide entitled “MedRadio Device Applications” showing the range of neurological and diabetes wireless device applications that could be supported in these bands.

Please contact the undersigned if you require any additional information.

Sincerely,

John W. Kuzin

John W. Kuzin
Counsel to Medtronic Inc.

Attachments

cc: Charles Mathias

MEDRADIO RULEMAKING

The Commission Should Authorize The Proposed MEDS Wing-Bands at 401-402 and 405-406 MHz And Maintain The Established MICS Rules at 402-405 MHz; ET Docket No. 06-135, RM-11271

Proposed Wing-Band Rules. The FCC should approve the proposed 401-402 and 405-406 MHz wing band allocation because it will spur development of a wide variety of wireless body-worn and implantable medical devices. The MedRadio NPRM proposed a two-tier regime supporting: (1) devices that perform spectrum sensing (Listen Before Transmit or “LBT”) and are frequency agile, and (2) other wireless medical devices that operate at ultra-low-power and with a low duty cycle.

The FCC’s proposals, which are consistent with Medtronic’s Rulemaking Petition and an ETSI standard, will support collocated medical body area networks. These devices will provide (i) improved patient care, mobility, and comfort, (ii) faster, more thorough diagnosis and therapy, (iii) enhanced monitoring tools, (iv) electronic recordkeeping, and (v) reduced clinical errors.

For Non-Voice Medical Applications Only. The FCC should maintain its restriction on non-voice communications in the MEDS and MICS bands. Allowing wireless hearing aids in any portion of the MedRadio band would result in an exclusive audio allocation because the devices are “on” all the time, would cause interference to non-voice medical devices and be inconsistent with international standards.

Despite the existence of wireless hearing aid systems that operate in other bands, such as low-power inductive systems from Oticon, Phonak and Siemens, chip maker ON Semi wants to use the band for wireless hearing aids and to stream audio. *See* May 1, 2008 ON Semi *Ex Parte* at 5. Medical device industry association AdvaMed and its members St. Jude Medical, Medtronic, Boston Scientific/Guidant, and Biotronik as well as chip maker Zarlink are united in their support for exclusive use of the bands by non-voice medical applications. *See* AdvaMed Dec. 4, 2006 *Ex Parte*; Zarlink Oct. 27, 2008 *Ex Parte*.

The Established MICS Rules. The Commission should reaffirm its Medical Implant Communications Service (“MICS”) regulations, which were first promulgated in 1999, with a limited exception to permit ultra-low-power, 0.01% duty-cycle operation at 403.65 MHz. There are already several hundred thousand implanted wireless medical devices in operation worldwide, and this number will continue to grow as the population ages and applications expand. Nonetheless, the FCC appropriately has noted that “the MICS device industry itself is still in its nascent stages and, absent compelling reasons, we would be reluctant to upset the existing MICS rules for operation in the 402-405 MHz band in light of research and development that has taken place in reliance on our rules, and the products that are and will soon be available to the public as a result.” *MedRadio NPRM* ¶ 24.

MICS implantable devices are a special class of RF devices that is separate from but complementary to the proposed MEDS devices. MICS implantable devices have far greater battery constraints and more stringent reliability requirements than most external devices: (1) they must be small enough to fit comfortably inside the human body; (2) they must be very power efficient for the same battery that supports wireless communications must also power therapeutic and diagnostic operations; (3) they must last seven to ten years following implantation; and (4) they can be replaced only via surgery, which introduces much more risk to the patient than battery replacement in external devices.

Wireless medical devices that operate in the core MICS band must “listen before transmit” and be frequency agile to ensure that critical medical communications are received. Interference from non-compliant devices causes re-transmissions by MICS devices, which impacts implant battery life. Physicians and patients need and expect an RF environment that is reliable and interference free. The self-regulatory spectrum management tools in the current MICS rules (*i.e.*, frequency agility, LBT) provide that reliability.

MedRadio Device Applications

Neurological
and Diabetes

COMMERCIAL

- Tremor
- Peripheral Vascular Disease
- Chronic Pain
- Malignant Pain
- Spinal & Cerebral Spasticity
- Liver Cancer
- Gastroparesis
- Diabetes
- Urinary Incontinence

IN DEVELOPMENT

- Parkinson's Disease
- Dystonia
- Obsessive-Compulsive Disorder
- Depression
- Epilepsy
- Occipital Neuralgia
- Angina Pain
- Nonopioid Pain
- Obesity
- Diabetes
- Interstitial Cystitis
- Bowel Disorders

Therapy
and Market
Development

- MiniMed Pump
- Drug Delivery
- Neurostimulation



Medtronic

Alleviating Pain · Restoring Health · Extending Life

Wireless-enabled medical devices will continue to proliferate.