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May 18, 2006

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ET Docket No. 06-135

VIA ELECTRONIC MAIL

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

Re: 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 follows up on our recent discussions concerning the petition that Medtronic filed requesting the creation of the Medical Data Service ("MEDS") and how that service would interplay with the existing Medical Implant Data Communications Service ("MICS"). The MEDS Petition for Rulemaking was filed in July 2005, and comments and reply comments on the Petition were filed in September and October 2005. Not only will MEDS advance the Commission's objective of encouraging "the provision of new technologies and services to the public" as set forth in Section 7 of the Communications Act, 47 U.S.C. § 157, it will also further the Administration's efforts to improve health care through greater use of information technology.

Medtronic also is pleased to inform the FCC that the FDA recently approved the Medtronic Concerto and Virtuoso line of cardiac devices with MICS capabilities. As the attached press release notes, the wireless MICS capabilities support a number of advances in the remote monitoring of patients as well as efficiencies at device implant and follow-up visits to the physician's office. Cardiologists across the United States also now have the MICS programmer/controller to use with these new devices.

Attached to this letter is a more detailed response to questions raised by OET staff, but let me briefly highlight some of those points:

The Need for Separate Bands. MICS and MEDS support different, but often complementary, medical devices. Their different functions necessitate different product design, particularly with regard to power supply, and consequently require different regulatory frameworks so that patients and physicians are relieved of the burdens of spectrum management. Both services should operate under regulations

that foster efficient spectrum management and help ensure that time-sensitive, life-critical data are received reliably.

Device Differences. Devices that are planned for operation in the MICS band will generally be implanted deeper than devices that would operate in MEDS, and they have far greater battery constraints. Conserving implant battery life is particularly critical for MICS devices. MICS band implants use the same power source for both therapeutic and diagnostic operations as well as communications. Because the devices are typically implanted more deeply that MEDS implants, replacement of the MICS battery and/or the device is not simple and entails more risk to the patient than does the replacement of the battery used in body-worn devices or short-term transcutaneous implanted MEDS devices, some of which will likely involve replacement of the battery by the patient. Replacement of MICS band implants will generally require major surgery and involve replacement of not just the battery but the entire device.

Rules to Minimize Interference and Conserve Implant Battery Power. The regulatory structure should foster an environment in which those devices that can least afford frequent battery replacements are operated in a manner that minimizes the need for additional activities that consume power. While listen before transmit ("LBT") and adaptive frequency agility ("AFA") are to be employed in MICS in order to reduce the probability of receiving interference, the more power that must be devoted to LBT/AFA operations, the more rapidly the battery will be depleted. Hence, MICS is structured to provide both for efficient spectrum management and minimal expenditure of precious battery power by the implanted medical device.

MEDS Flexibility. MEDS, too, will need to be reliable and may involve the transmission of life-critical, time sensitive-data from body-worn sensors and even some implanted devices. But unlike medical implants for which MICS was designed, MEDS devices will typically include body-worn sensors that have external batteries that can be replaced more easily. Additionally, because expenditure of power for MEDS devices does not exact the same high price in terms of replacement expense and patient risk that replacement of batteries for MICS implants would entail, MEDS can support the carefully restricted use of non-LBT/AFA devices at lower power and lower duty cycles. In this manner, devices that do not support LBT/AFA but transmit useful – but non-time-sensitive – medical data can operate in MEDS. Placement of such devices in MICS would subject other devices to needless use of power in an effort to avoid or overcome the effects of interference.

Technical Rule Differences. The differences in the types of devices that MICS and MEDS will support also explain why the MICS rules call for 300 kHz maximum channel bandwidth and the MEDS petition proposes a 100 kHz maximum bandwidth. MICS implant devices will often record relatively large amounts of data for transmission. Use of the larger bandwidth will facilitate shorter, more efficient, transmissions. MEDS devices will generally not be under the same battery constraints as MICS devices. The use of 100 kHz wide channels for MEDS will make available up to 20 such channels. With the expected proliferation of MEDS devices, a 100 kHz channel bandwidth provides a greater number of available channels for use in Body Area Networks comprised of multiple sensors (effectively, local patient "hot spots"). Multiple-sensor systems will allow a physician to analyze data from multiple simultaneous sources and improve the accuracy of the diagnosis.

International Harmonization. The MICS band, at 402-405 MHz, already has emerged as the worldwide standard for active medical implant communications. Aside from the FCC, the European Union, the European Free Trade Association countries, Japan, Australia, and Canada have adopted regulations generally consistent with the MICS rules. Like MICS, the MEDS allocation in the "wing-bands" at 401-402 and 405-406 MHz would be compatible with international allocations.

International harmonization would serve the public interest by offering the international traveler with implanted or body-worn medical device technology an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention whether at home or abroad. International compatibility also would allow development costs to be spread among multiple national markets.

First Do No Harm. Finally, it is important to keep in mind that if the experience gained under MEDS reveals that non-LBT/AFA devices operating at lower power and with low duty cycles can be employed in MICS with minimal impact on more deeply implanted devices that use LBT/AFA, it will be relatively easy to amend the rules to allow migration from the MEDS bands to the MICS band. The converse, however, is not true.

If the Commission proceeds to expand the available spectrum without maintaining the distinctions between MICS and MEDS, it will be very difficult and disruptive to put the pieces together to separate these bands to support different needs. As such, Medtronic urges the Commission to move forward with the adoption of a notice of

proposed rule making calling for the adoption of the rules proposed in Medtronic's Petition.

Sincerely,

/s/ Robert L. Pettit

Robert L. Pettit

Attachments. News Release – Medtronic Receives FDA Approval for New Cardiac Systems with Distance Wireless Telemetry

Responses to Questions from OET staff

cc: Daniel Gonzalez
Fred Campbell
Aaron Goldberger
Bruce Gottlieb
Barry Ohlson
Rashmi Doshi
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News Release

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Medtronic Receives FDA Approval for New Cardiac Systems with Distance Wireless Telemetry

Concerto CRT-D and Virtuoso ICD transmit patient data remotely and automatically to physicians, enabling better care

MINNEAPOLIS - May 17, 2006 - Medtronic, Inc., (NYSE: MDT) today announced United States Food and Drug Administration approval of the Medtronic Concerto™/Virtuoso™ line of implantable cardiac devices, Medtronic's next generation of cardiac rhythm disease management products. The approval coincides with Heart Rhythm 2006, the Heart Rhythm Society's 27th Annual Scientific Sessions - the pre-eminent gathering of medical professionals from across the globe who specialize in the heart's rhythms and electrical function. Market availability of these devices will follow in June 2006.

The Concerto cardiac resynchronization therapy-defibrillator (CRT-D) and Virtuoso implantable cardioverter defibrillator (ICD) are the first implantable cardiac devices available with Medtronic's proprietary Conexus™ Wireless Telemetry, developed using the Medical Implant Communications Service (MICS, 402-405 MHz). Using the MICS band enables reliable communication between the implanted device and clinician programmers and patient home monitoring units.

Conexus Telemetry will enhance efficiencies at device implant and during in-office follow-up visits. At implant, there is no need for the programmer head to enter the sterile implant field, and in-office visits may be simplified when they're needed, as the physician can interrogate patients' devices via wireless telemetry without the need for surface electrodes. As well, Conexus Telemetry will enable automatic, wireless data transmission from the patient's device to a home monitor. Device data then will be transmitted to the clinician using the Medtronic CareLink® Network, the first Internet-based system to help physicians and patients better manage chronic cardiovascular disease treated by implantable device therapy. Communication between device and monitor will be initiated by physician-programmed device parameters or it can occur on pre-scheduled dates that are pre-programmed via the Medtronic CareLink Network. If the system detects notable changes in the patient's condition or device status, a Medtronic CareAlert™ will be sent to the physician, providing the potential for treatment decisions before the condition worsens.

"Implantable device therapy is entering a new era with innovation focused on overall cardiac disease management and enhancing patient quality of life," said Charles Haffajee, M.D., director of Cardiac Electrophysiology, Arrhythmia and Pacing at Caritas St. Elizabeth's Medical Center in Boston. "This system's features, in combination with wireless distance telemetry, offer more convenient, yet equally effective, device management and patient care."

The Virtuoso ICD and Concerto CRT-D help track and manage heart failure symptoms. They also will deliver a shock to terminate a dangerously abnormal heart rhythm. The Concerto CRT-D device also sends tiny electrical impulses to the heart muscle to resynchronize the contractions of the heart's lower chambers, helping the heart pump blood throughout the body more efficiently. Other features include:

- Conexus Wireless Telemetry with SmartRadio™: Utilizing the MICS radio frequency band, Medtronic Conexus Telemetry enables reliable communication between the patient's implanted device and home monitor or clinician programmer at a range of two to five meters (approximately six to 16 feet). The MICS band is a frequency designated by global telecommunications regulatory authorities, such as the Federal Communications Commission, for implantable medical device communication. Use of the MICS band protects Medtronic wireless devices from interference caused by cell phones and other common wireless devices, providing a level of protection that cannot be offered by systems that use other frequencies.

- OptiVol® Fluid Status Monitoring: OptiVol measures changes in impedance in the thoracic cavity, the chest area encompassing the lungs and heart. Using very low electrical pulses that travel across the thoracic cavity, the system can measure the level of resistance to the electrical pulses, which indicates the level of fluid in the thorax. Since normal fluid levels may vary from patient to patient and fluid accumulation can be either slow or rapid, OptiVol's ability to measure fluid status trends over time can provide important insights used in conjunction with ongoing monitoring of other patient symptoms. Previously available on the Medtronic InSync Sentry™ CRT-D device, OptiVol is now available to Virtuoso ICD patients as well as Concerto CRT-D patients.

- Left Ventricular Capture Management: LVCM, available on the Concerto CRT-D, is intended to automatically sense and adjust impulses for optimal stimulation of the heart's lower left chamber (ventricle) and ensure cardiac resynchronization therapy.

- ATP During Charging™: Automatically uses pacing pulses to painlessly stop fast, dangerous heartbeats, while concurrently preparing to deliver a shock if needed, with no delay. Medtronic PainFREE™ Therapy has been clinically proven to eliminate three out of four shocks with painless pacing therapy. ATP During Charging is now available for both CRT-D and ICD patients.

- Managed Ventricular Pacing: MVP™ Mode, available on the Virtuoso DR (dual chamber) ICD, promotes intrinsic conduction and reduces right ventricular pacing by 99 percent (median).

"Packaging remote and wireless patient monitoring with several of Medtronic's other market-exclusive features into the Concerto/Virtuoso line of implantable devices represents the best industry has to offer in cardiac rhythm and disease management," said Steve Mahle, president of Medtronic Cardiac Rhythm Disease Management.

Heart failure afflicts 5 million Americans and is the number one cause of hospital admissions, with most of these admissions due to fluid accumulation in the thorax. This fluid buildup often goes undetected until the patient is critically ill, and it is not unusual for patients to require hospitalization or urgent treatment at an emergency room for severe respiratory distress. With approximately 1 million hospitalizations each year for heart failure, heart failure management is a tremendous cost burden to the country's healthcare system.

For more information about the Concerto/Virtuoso line of implantable cardiac devices with Conexus Wireless Telemetry, visit www.MedtronicConexus.com.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Quarterly Report on Form 10-Q for the quarter ended January 27, 2006. Actual results may differ materially from anticipated results.

Medtronic, Inc. 2006

RESPONSES TO OET QUESTIONS

Why should the agency develop different rules for MICS and MEDS?

The Medical Implant Communications Service ("MICS") and MEDS should be maintained in separate bands because the communications needs and battery limitations of deep medical implants (which in most cases would be supported by MICS) are very different from those of short-term transcutaneous implants and body-worn medical devices (which would be supported by MEDS).

Almost every patient who undergoes a major surgical procedure to obtain a medical implant does so because the patient needs the medical device to support certain life-critical functions. In undergoing such a serious procedure, the patient and the attending physician understandably expect the implant to operate reliably for a number of years before it will need to be replaced. Today's cardiac implants, for example, operate for five to seven years before replacement is required. And, in most cases where replacement is required, it is only because the implant's battery is depleted.

Deep medical implants must be as small and lightweight as possible to fit comfortably within the human body. Because the battery that powers the medical implant must likewise be very small but also last for a number of years, the implant with MICS communications capabilities must be meticulously engineered to occupy very little space and draw very little power.

At the same time, the MICS transceiver must be designed to meet stringent reliability requirements with close attention to operational range, transmission rate, and power supply constraints. MICS uses Listen Before Transmit ("LBT") and Adaptive Frequency Agility ("AFA") interference avoidance protocols so that the low-power transmissions from the implant are successfully received. These protocols play a critical role in maintaining the long battery life of deep medical implants. Any time an implant is required to retransmit data, precious battery capacity is depleted.

MICS was developed to typically provide a long term communications solution for implanted medical device and external programmer/controllers. The maximum transmit power level for both devices is 25 μW EIRP outside the body. However, RF implants use much lower transmit power levels (*i.e.*, approximately 100 nW EIRP) for these reasons. For RF devices embedded in human tissue, antenna gains are negative and tissue absorption is significant. The combination of these factors results in 20-30 dB of input power versus radiated EIRP. RF exposure limits are also a factor. Even with an transmit EIRP of 1 microwatt and 20-30 dB of attenuation, the RF power output in the body would be 1 mW or only 3 dB below the SAR limit of 1.6 mW/g. If implants were to use a much higher transmit power level, they would easily exceed the SAR limit. Thus as a practical matter, implants are very limited in their EIRP levels and become the limiting factor for both communications range and relative C/I ratios (robustness) that are critical to successful communications.

Transcutaneous implants and body-worn medical devices, however, such as those that would operate in MEDS, generally are not so limited. Typically, these devices are used for shorter periods of time and are more easily removed from the patient. Most importantly, the battery powering these devices often is readily accessible (and hence easily replaceable). Thus, short-term transcutaneous implants and body-worn medical devices do not have the same power limitations as deep implants.

If MEDS devices are intermixed with MICS devices, there would be less available spectrum for time-critical MICS communications from deep medical implants in areas of high use, such as hospitals, physician's offices and nursing homes. The problem would become especially severe as transcutaneous and body-worn devices become increasingly widespread. As a result, implanted MICS devices would be forced to compete for channel access with higher-power, body-worn devices. This unfortunate situation, which would unfairly penalize MICS devices, conflicts with the purpose of the MICS band and could thwart the future potential of the MICS band. Therefore, MEDS devices should operate in spectrum that is separate and apart from MICS.

Why can't LBT/AFA and non-LBT/AFA devices coexist in the same band? If LBT/AFA and non-LBT/AFA devices can coexist in the "wing" bands, why not in the MICS band?

The use of LBT and AFA is essential to systems that support life-critical communications from deep medical implants (*i.e.*, MICS). Non-LBT/non-AFA devices – that transmit at will and frequently – cannot co-exist over the long term with deep medical implants operating in the MICS band because these devices will interfere with power-limited implants that rely on interference avoidance mechanisms, resulting in premature battery depletion and potential critical communication loss.

If the FCC were to allow non-LBT/non-AFA operations in the MICS band at this juncture and such operations introduce harmful interference to implanted devices that rely upon LBT and AFA, it will be very difficult, if not impossible to undo the disastrous situation. If on the other hand, the experience gained through the MEDS indicates that LBT/AFA can coexist with restricted non-LBT/non-AFA operations (that is, low-power, low-duty-cycle transmissions), it will be relatively simple to open the MICS band to such operations at a later date.

Life-critical, time-sensitive communications from implanted medical devices, which include notification of device malfunctions and other life-threatening conditions, must be successfully received and acted upon promptly, if not immediately. These communications call for an added degree of care.

For example, when a surgeon is implanting a pacemaker or a defibrillator and positioning leads to the heart or adjusting the implant's parameters while monitoring the physiological effects, the RF communications link to the device must be low latency (typically less than 200 ms) so that the information from the electrocardiogram (ECG) is presented in (near) real-time. In cases where the duration of the interference exceeds the buffering capability of the system (which is directly related to the allowable link latency), life-critical, time-sensitive data could be lost.

However, as the MEDS Petition illustrates, non-LBT/non-AFA devices, with appropriate restrictions, can coexist with certain types of medical devices that support LBT and AFA. Medtronic believes that the two-tiered structure proposed in the MEDS Petition for Rulemaking strikes an appropriate balance. The MEDS permits operations for medical devices that do not implement LBT and AFA so long as the devices use lower transmit power (250 nW, relative to the 25 μW maximum power level allowed for LBT/AFA operations) and a low duty cycle (0.1 % or less, which is no more than 3.6 seconds of transmit time in one hour). Medical device communications that require more intensive use of the spectrum and/or increased reliability will need to implement LBT and AFA.

In this way, MEDS would offer an alternative to MICS band for implant devices that transmit non-life-critical data (*e.g.*, periodic reports) via non-LBT/non-AFA operations. The MEDS low-power, low-duty-cycle ("LPLDC") mode of operation preserves the majority of "on-air" time in the MEDS for devices that perform LBT and AFA, which are well established, self-regulating spectrum sharing tools.

Why are implantable devices allowed in the MEDS?

Medtronic envisions that MEDS and MICS would be complementary medical communications services that could be integrated into the same medical equipment. The close proximity of the two services offers medical device manufacturers implementation flexibility, which could include a single transceiver module (*e.g.*, a Body Area Network "manager") that communicates with medical devices operating in both the MEDS and MICS.

MEDS, which will be adjacent to the MICS band, will make use of the low-power, miniaturized RF transceiver technology that was developed for MICS. Medical implant device operations that require reliable communications for life-critical data will use the MICS band, while short-term transcutaneous implants and body-worn medical devices (which unlike deeply implanted devices are not as limited by power and size constraints), and LPLDC non-LBT/non-AFA medical implants will operate in the MEDS band.

Why is LBT/AFA critical for MEDS?

Self-regulating, interference avoidance tools such as LBT and AFA are needed in any band that will be used for "higher powered" (*i.e.*, 25 μW) medical communications associated with patients and patient care. At the same time, Medtronic recognizes the need for operational modes that do not use LBT and AFA for non-time-critical medical communications, and, for this reason, proposed the two-tiered device operation in the MEDS Petition. The low-power, low-duty-cycle limits placed on this mode of operation would enable successful sharing with medical devices that make intensive use of the MEDS spectrum. Medical operations that require increased reliability, higher transmit power, or desire to make more intensive use of the spectrum would need to use LBT and AFA to enable successful communications and avoid interference.

Why are some of the technical requirements proposed for MEDS different from those in the MICS band?

As described above, MEDS was proposed to support different medical needs from those supported by MICS. Therefore, some of the operational requirements are different.

The MICS rules, which were designed to support life-critical, time-sensitive communications from deep medical implants, recognize the critical limitations of this special class of medical devices. Specifically, deep implants must be small in size, contain very small batteries, and be extremely power efficient. Wider bandwidths of up to 300 kHz for MICS allow transmission of larger amounts of data in less time, allowing medical implants to limit "on-air" time to conserve power. Given that MICS occupies 3 MHz of spectrum, the 300 kHz maximum bandwidth provides for 10 channels.

The draft MEDS rules, while based to a great extent on the MICS regulations, do allow low-power, low-duty-cycle ("LPLDC") operation as outlined above. The 250 nW proposed power level for the LPLDC operation provides for communications to an external receiver that is worn by the patient or placed on a bedside table.

With the expected proliferation of MEDS devices, a 100 kHz channel bandwidth provides a greater number of available channels for use in Body Area Networks comprised of multiple sensors (effectively, local patient "hot spots"). Multiple-sensor systems will allow a physician to analyze data from multiple simultaneous sources and improve the accuracy of the diagnosis.

Furthermore, most METAIDS radiosondes (with whom MEDS would share the spectrum) have an emission bandwidth of 300 kHz (and a low-accuracy frequency reference). With 100 kHz-wide MEDS channels, if a radiosonde drifts into either segment of the MEDS band, a significant number of non-blocked channels would be available. If the proposed maximum channel bandwidth for MEDS was 300 kHz, a single radiosonde could interfere with two of a total of six 300 kHz "channels" (33%), leaving only four channels available within the radiosonde footprint.