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September 21, 2007

By Electronic Filing

Ms. Marlene H. Dortch
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Re: ET Docket Nos. 06-135 & 05-213 and RM-11271
Ex Parte Presentation

Dear Ms. Dortch:

Biotronik, Inc. ("Biotronik") hereby responds to an *ex parte* letter of September 13, 2007, filed by Medtronic in the above referenced proceeding, wherein Medtronic responded to a query by Office of Engineering and Technology ("OET") staff regarding international medical implant device rules. Specifically, Medtronic addressed the following two questions posed by the staff:

1. What countries have authorized wireless implantable medical device communications consistent with the Commission's Medical Implant Communications Service ("MICS") regulations; and
2. Whether the MICS regulations permit operation of an RF device that operates on a single channel within the 402-405 MHz band, or in other words, is not frequency agile.

With regard to the first question, Biotronik believes that Medtronic's *ex-parte* letter is correct in its list of countries and their respective radio regulations for MICS. Medtronic's response to the second question, however, is incomplete in that it focuses only on the Commission's present MICS regulations and does not give an accurate picture of comparable regulations in other countries. Biotronik provides this information below.

Worldwide Availability of MICS Transceivers without Adaptive Frequency Agility

More than 40 countries currently have authorized the use of Low-Power Low-Duty Cycle ("LP-LDC") operation on a single channel within the MICS band, *i.e.*, without frequency agility.¹ This is the approach also urged upon the Commission by Biotronik, St. Jude Medical, Boston Scientific/Guidant, DexCom, and AMI Semiconductor, as noted in each of the respective comments and summarized in Biotronik's previous filings in these proceedings.²

Regulations in Other Countries Currently Are Being Modified to Allow LP-LDC

Additionally, international radio regulations are being modified in other countries to also permit operation of a medical implant device that operates on a single channel within the 402-405 MHz band, or in other words, is not frequency agile. For example, the Asia-Pacific Telecommunity ("APT") Wireless Forum unanimously adopted a recommendation for its 34 government administration members to permit the use of LP-LDC on a single channel within the MICS band.³ The APT Management Committee will formally record this recommendation at its November 2007 meeting in Korea. Even though the formal recording process is not quite complete, a number of administrations

¹ The countries that allow LP-LDC on a single channel within the MICS band include: Australia, Canada, New Zealand, Japan, China, Iceland, Liechtenstein, Norway, Switzerland, Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Croatia, Monaco, Singapore and Vietnam.

² See *Letter from Henry Goldberg, Attorney for Biotronik, Inc., to Marlene Dortch, Secretary, Federal Communications Commission, Attachment A (May 23, 2007) ("Biotronik Presentation")*.

³ See APT AWF Document AWF-3/54. APT members include: Afghanistan, Australia, Bangladesh, Bhutan, Brunei Darussalam, Cambodia, China, Fiji, India, Indonesia, Iran, Japan, South Korea, North Korea, Laos, Malaysia, Maldives, Marshall Islands, Micronesia, Mongolia, Myanmar, Nauru, Nepal, New Zealand, Pakistan, Palau, Papua New Guinea, Philippines, Samoa, Singapore, Sri Lanka, Thailand, Tonga and Vietnam. Associate Members include: Cook Islands, Hong Kong (China), Macao (China) and Niue.

have already implemented the recommendation, including Australia, China, New Zealand, Japan and Vietnam.

LP-LDC in the MICS Band Provides an Efficient Method to Access the Band

LP-LDC is a simplified access method that reduces the timing and synchronization requirements between implants and external devices. It reduces spectrum usage and transmission latencies and enables less complex radio design and lower power consumptions.⁴

The FCC MICS Rules Should be Harmonized Internationally

Biotronik strongly agrees that internationally harmonized MICS regulations will serve the public interest, both by facilitating international travel of individuals with implantable medical devices, allowing them to receive appropriate medical attention abroad, and lowering the cost of these devices by allowing for economies of scale. Biotronik urges the FCC to allow Americans to reap the benefits of international harmonization by adopting the use of LP-LDC within the center channel of the MICS band.

Please direct any questions to the undersigned.

Sincerely,

A handwritten signature in black ink that reads "Henry Goldberg". The signature is written in a cursive, flowing style.

Henry Goldberg
Attorney for Biotronik, Inc.

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

⁴ See Comments of Biotronik, Inc. at 10-14 (filed Oct. 31, 2006).