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VIA ELECTRONIC FILING

Marlene H. Dortch, Esq.
Secretary
Federal Communications Commission
Washington, DC 20554

Re: *Ex parte* Notice
Biotronik Request for Waiver Of MICS Frequency Monitoring Requirements – ET Docket 03-92

Dear Ms. Dortch:

This is to note that on January 22, 2004, Robert L. Pettit and I as counsel for Medtronic, Inc., met with Commissioner Jonathan S. Adelstein and his Legal Advisor Barry Ohlson to discuss the above-referenced Biotronik waiver request. A copy of the material provided to Commissioner Adelstein and Mr. Ohlson summarizing Medtronic's position is attached.

Please contact me with any questions concerning this matter.

Respectfully,

/s/ David E. Hilliard

David E. Hilliard
Counsel for Medtronic, Inc.

Attachment

Cc: The Honorable Jonathan S. Adelstein
Barry Ohlson, Esq.

Biotronik Waiver: Needless Risk and Congestion in the Medical Implant Band

Biotronik has requested a waiver of the interference protection provisions of the Medical Implant Communications Service (MICS) rules that require medical devices operating at 402-405 MHz to "listen before transmitting" (LBT). LBT is a simple, self-regulating interference avoidance mechanism that will allow the significant proliferation of advanced, life-critical medical devices. It's a fundamental building block of cognitive radios, has been required for new wi-fi band operations, and is a technique used in land mobile radio. Biotronik's implant devices cannot perform LBT. That's why Biotronik is asking for a waiver. Once the doors to unreliable non-LBT operations are opened, it will be difficult to restrict future non-compliant operations – and Biotronik's old technology will drive out the new LBT-based technology for which MICS was designed. While that undoubtedly serves Biotronik's short-term business interests, it does not serve the long-term public interest of providing access to advanced, reliable, life-critical RF medical devices.

- Despite Biotronik's efforts to divert attention, the real question here is not the medical usefulness of its implant devices. The real question is why Biotronik's old-technology devices need to operate in a limited band that the Commission created for reliable RF medical devices. The record is clear: Biotronik's devices don't need to operate in the MICS band. Transmit-only (non-LBT) medical devices for non-life critical transmissions, similar to Biotronik's, already operate in other internationally available spectrum – most notably 433 MHz.

- Likewise, if Biotronik's old unreliable technology is allowed unlimited use of the MICS band, there is a very real risk that MICS will become a medical CB band – less and less useful as the limited bandwidth is sucked up by more and more potentially interfering non-LBT transmissions.

- This risk is even worse given the nature of Biotronik's request. While certain operating parameters have been identified, Biotronik's waiver request asked for unlimited authority to transmit at maximum power with no limit on the number of transmissions, the transmission duration, or the frequency of transmissions. Also, the waiver request would arguably permit the development of a higher-powered external controller that operates without LBT.

- If the Commission grants any form of waiver to Biotronik, it must be carefully circumscribed. In line with NTIA's stipulated conditions, any waiver should specifically state that:
  - Operation is limited to marketing and human implantation of cardiac implants for one year from the date of issuance of the Commission's order.
  - Operation is limited to cardiac implants only and not to any external equipment.
  - Operation is limited to the precise device characteristics stated in the Request for Waiver as modified by Biotronik's September 24, 2003, *ex parte* filing.
  - There is a very real risk of interference to Biotronik's implant device transmissions from Part 15 devices, other MICS devices, and Meteorological Aids devices.
  - Operation is limited to non-life critical communications the failure of which will not impact the health and safety of an implant patient.
  - Medical professionals and potential implant patients must be informed of these conditions.
- These conditions require strict FCC monitoring given Biotronik's past behavior. Biotronik just hasn't played straight – with the Commission, with physicians, or with consumers. As the record of this proceeding shows, rather than comply with OET's March 8, 2002, order to modify its implants to comply with the MICS rules, Biotronik launched a broad-based marketing campaign announcing the availability of its unmodified RF implants in the U.S. – in breach of FCC marketing rules. Biotronik also used the experimental radio rules to market its implants but was unwilling to inform physicians and consumers of the experimental nature of the operation.