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VIA ELECTRONIC FILING

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

Re: Biotronik Request for Waiver Of MICS Frequency Monitoring Requirements – ET Docket 03-92
***Ex parte* submission of Australian TGA Comment on Australian Communications Authority Proposals Paper**

Dear Ms. Dortch:

The Australian Therapeutic Goods Administration (“TGA”)¹ has voiced serious concerns about the “safety and performance of one-way fixed channel telemetry systems for medical implants” in a Comment on the Medical Implant Communications Service (MICS) Proposals Paper issued by the Australian Communications Authority (“ACA”). A highlighted copy of the TGA’s Comment is attached to this letter.

The TGA’s Comment reveals that Australia rejected an application for a one-way implantable device with limited MICS functionality – such as the Biotronik suite of implants that are the subject of the above-referenced waiver petition before the FCC – based on insufficient evidence that the device could perform reliably in Australia’s RF environment. The TGA and the ACA jointly examined the application for a one-way telemetry implant device for nearly one year.

On January 6, 2004, Medtronic advised the FCC of the ACA’s MICS Proposal Paper. *See* Ex Parte Comments of Phillip Inglis, technical consultant to Medtronic, Jan. 6, 2004. Medtronic noted that the Australian Authority specifically considered one-way telemetry devices proposed for operation in the very crowded 403 - 403.9875 MHz mobile radio sub-band, and found that introduction of the devices would “increase substantially the likelihood of unavoidable interference to the operation of these devices.” *See id.* at 3-4. In addition, the ACA relied upon the current U.S. and European MICS regulations in implementing consistent regulations

¹ The Therapeutic Goods Administration is the Australian counterpart of the United States’ Food & Drug Administration (“FDA”).

Marlene H. Dortch
January 14, 2004
Page 2

to support advanced medical RF services to implant patients who travel throughout the world.

The FCC should review carefully the Australian government's position, as expressed in the ACA Proposal Paper and TGA Comment. Citing reliability concerns, Australia has made clear that only fully compliant MICS devices that incorporate interference avoidance mechanisms, such as LBT and frequency agility, should operate in the limited MICS spectrum. Indeed, as the FCC recognized less than one year ago, interpretation of the MICS rules "as urged by Biotronik, to permit regular and potentially frequent transmissions with no specific instigation, would effectively eviscerate the protective provisions of the rules, and we cannot interpret our rules such that they have no effect." *Biotronik, Inc. Equipment Authorization for the Medical Implant Communications Service, FCC Identifier PG6BAOT, Memorandum Opinion and Order*, 18 FCC Rcd 3027, rel. Feb. 25, 2003.

Medtronic strongly opposes any waiver grant to Biotronik. Nevertheless, should the Commission find that a limited term waiver is in the public interest, it should be circumscribed according to the conditions that Medtronic and NTIA have proposed.

Respectfully,

/s/ John W. Kuzin

John W. Kuzin
Counsel for Medtronic

Att.

cc (via email): Mr. Sam Feder
 Mr. Julius Knapp
 Ms. Jennifer Manner
 Mr. Paul Margie
 Mr. Barry Ohlson
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 Mr. Ed Thomas
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File Reference: 2003/073913

**COMMENT ON THE ACA PROPOSALS PAPER:
*Planning for Medical Implant Communications Systems (MICS)
& Related Devices, October 2003.***

Thankyou for the opportunity for the TGA to comment on the ACA planning proposals in relation to the operation of MICS equipped devices in Australia, as described in the above Proposals Paper.

Over the last year there have been several telephone conversations and email correspondence between staff of the TGA and the ACA in relation to MICS, triggered by an application by a medical device supplier to enter an implantable device with limited MICS capability on the Australian Register of Therapeutic Goods. That application was subsequently rejected by the TGA on the basis that evidence was not provided to demonstrate that MICS would perform as intended in the Australian environment. This was a rejection of the available evidence for that particular product and not a rejection of MICS in general.

The TGA welcomes the ACA proposal to introduce regulatory arrangements that would support the operation of fully MICS compliant devices in Australia. It is noted that this is proposed to be on a no-protection no-interference basis. This necessarily limits the uses to which this technology can be reliably applied, but this is consistent with the arrangements in place in other countries where MICS currently operates.

The analysis in the Proposals Paper appears generally sound. However, the following issues should be considered:

- The analyses assume that external MICS programmer/controller equipment will be located in hospitals or specialist medical clinics. This assumption contributes to the conclusion that interference between MICS equipment and offshore radiolocation and land mobile systems (LMS) will be unlikely. However, MICS applications and products in which the external programmer/controller equipment is mobile or based in patients' homes are quite likely. An example of such a system is the implantable device with limited MICS capability described above.
- The analyses assume that MICS usage in remote areas will be unlikely. This appears to be based on low population densities and on the previous assumption described above. This may be valid in the broadest sense, however the paper does not consider the consequences for rural or remote patients with MICS-equipped implants. In particular, mobile MICS service coverage may be geographically limited in practice.

- The proposal allows MICS implants to normally transmit only when communications are initiated by programmer/controller equipment. However in the case of "medical implant events" the implant is allowed to initiate communications. The Proposals Paper does not take into account the potential nature of these "medical implant events", which may often indicate an imminent life-threatening condition for the patient. Furthermore, there is no consideration of the associated MICS service coverage, reliability and trustworthiness issues.

The concerns expressed above should however be largely mitigated by the ability of fully MICS compliant devices to select from a range of available radio frequencies. If one or more of the MICS frequencies are in use in a particular locality, the programmer/controller can select a different frequency that is not in use.

The implantable device previously referred to appears to incorporate only part of the MICS specification. In particular, the system does not appear to fully implement the frequency agility requirements. For the reasons outlined above, the TGA is concerned about the safety and performance of these kind of one-way fixed-channel telemetry systems for medical implants. The TGA therefore has no objection to the ACA proposal to limit any new spectrum regulatory arrangements to fully compliant MICS devices, without allowance for one-way fixed-channel implant telemetry systems.

There is a residual risk that MICS service coverage, reliability and trustworthiness may be limited even for systems that fully comply with the MICS requirements. There may be rare instances or localities in which heavy use of the MICS radio spectrum makes implant telemetry unreliable. "Medical implant event" transmissions, because of their nature, may also not necessarily employ frequency agility techniques. The machine intelligence necessary for frequency selection will generally reside in the programmer/controller, rather than in the implant that is initiating the communication session.

The TGA therefore has some concerns about the ACA MICS proposal, but the MICS specification appears to reduce the risk to patients to an acceptable level, and the potential benefits are likely to exceed the risks for fully compliant MICS devices. Nonetheless, patients and their physicians should be made aware that the no-protection no-interference support for MICS equipped devices in Australia may result in limited service coverage in some localities and instances. Provided that this can be addressed, the MICS proposals should benefit Australian patients.

For further discussion on any of these issues, please contact John Jamieson.

Yours sincerely,

John Jamieson
Acting Manager,
Medical Devices Assessment Section
Office of Devices, Blood and Tissues
12 January 2004