

November 30, 2007

ELECTRONIC FILING

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

**Re: ET Docket Nos. 06-135, 05-213, 03-92, and RM-11271
Notification of Ex Parte Presentation**

Dear Ms. Dortch:

This communication responds to the Medtronic Nov 1, 2007 ex-parte submission in the above-referenced dockets. Medtronic's concerns will be discussed and addressed point-by-point in the following paragraphs.

On page 2 of its ex-parte submission, Medtronic recites from the Wireless Bureau's DA 07-801 response to the Transoma Request for Interpretation of MICS rules to permit use of the service for medical testing on non-human subjects. This recitation notes that the rules expressly refer only to implantation of MICS devices in humans. However, Transoma is not intending to debate the Commission's interpretation of the MICS rules but is appropriately responding to the outcome of the interpretation request. The Commission goes on to state the following within paragraph 5 of DA 07-801 (emphasis added):

The public interest benefits of extending the use of the MICS to medical research and development efforts is a matter that is properly considered in the **rulemaking** context, where those benefits can be weighed against other factors such as the interference impact of such expanded use.

Transoma has responded appropriately by submitting its request for expanded use to be considered as part of the RM-11271 **rulemaking**.

Medtronic expresses concern on page 3 of their ex-parte submission that the term "laboratory" may include locations in "countless office buildings, many residential settings, and healthcare facilities". The term "laboratory" is from slide 18 of the Transoma Sept 26, 2007 presentation to members of the Commission. Here, the term "laboratory" is used within the *Proposed Addition to Permissible MedRadio Communications* which is stated as "Devices in the MedRadio service may communicate within a **laboratory** environment to monitor research subjects for the purpose of improving human health, such as for the discovery, development, and testing of pharmaceuticals, medical devices, and surgical techniques".

The constraint on location includes the limitation that the devices are used to monitor research subjects. Research subjects may be human or animal. Human subjects are included within the current use of MICS since some diagnostic or therapeutic benefit to the patient is expected in a clinical trial. Animal research subjects are only found in a secure room (laboratory) where human contact is limited and controlled. This laboratory could be within a building of a pharmaceutical company that also has offices, or in the basement of a hospital that also delivers healthcare. However, animal laboratories are inherently isolated and secure to prevent transmission of disease to the animals, to provide a secure environment for the animals, and to insure confidentiality when pharmaceutical or medical device development is involved. The walls, floors, ceilings, and separation distance that provide this isolation and security also effectively attenuate the MICS emissions.

Transoma acknowledges that a patient with ambulatory use of MICS telemetry via a body-worn transceiver may be working within an animal facility. This subject is addressed on slide 16 of the Transoma Sept 26, 2007 presentation with the relevant bullet point shown below.

Should there be patients with ambulatory use of MICS telemetry working in an animal facility, LBT and AFA technology would allow compatibility. There would be many channels available since only one MedRadio channel would be needed to handle the data generated by all research subjects with a given area.

This statement anticipates ambulatory use of MICS, although most current MICS devices perform telemetry in the home or clinic environment. In addition to the required use of LBT and AFA, another way to alleviate concerns about any interference to human MICS applications would be to designate nonhuman-use as secondary to human-use.

Medtronic repeats the Transoma statement from slide 13 of the Sept 26, 2007 presentation which states that "902-928 MHz ISM band might be a choice". However, the next three bullets on the same slide (listed below) point out why this band is a poor choice.

- The lab animal environment tends to be a high tech, automated environment for reasons of security, environmental control, and the huge volume of data that is generated.
- This environment is likely to include wireless devices such as RFID, network links, wireless keyboards and mice, security alarms, video-monitors, voice links such as telephones, intercoms and headsets, and environmental monitors such as thermometers.
- These devices have the potential to create an adverse environment for an ISM-based biomedical telemetry system.

There is considerable existing and continued proliferation of 902-928MHz equipment in the laboratory environment. A biomedical telemetry system in the same band, with the very low level of radiated power characteristic of implants, would reasonably be expected to receive interference if located in this environment.

Only a small portion of MedRadio spectrum would be needed to monitor laboratory animals within any given area. Transoma anticipates that the most efficient spectrum usage approach is to use one wideband channel to monitor multiple animals in a given area or room. An adjacent area would use a different channel to avoid conflicts. The typical number of animals within one area would define a minimum channel bandwidth requirement of 300 KHz. This matches well with current MICS regulations but not with the 401-402 and 405-406 MHz "wingbands" where channel bandwidth may be limited to 100 KHz. The animal monitoring application could be served by the current 402 – 405 MHz MICS bandwidth, or the bandwidth of the wingbands alone would also be sufficient if 300 KHz channels were allowed. The Sept 26 Transoma proposal discusses use of the entire MedRadio band not knowing what the final technical regulations will be for the wingbands. The Commission in the Sept 26 meeting asked Transoma if either the 402 - 405 MHz band or the wingbands would be sufficient. Transoma responded that either choice would include sufficient spectrum, but to use the wingbands efficiently would require the ability to aggregate channels to a 300 KHz bandwidth, which is contrary to anticipated international usage.

Implantable devices with radio transceivers involve a unique set of technical and regulatory challenges, whether they are for humans or animals. The requirements for implants for humans and animals are similar for implant depth, battery life, implant size, data-rate, and telemetry range. These requirements lead to corresponding design tradeoffs relating to tissue attenuation of the signal, battery capacity, power consumption, bandwidth, and battery/ electronics/ antenna size. These tradeoffs have driven regulatory decisions such as the frequency selection, field-strength limit, channel width, LBT threshold, and need to test emissions using a tissue phantom. In addition, the requirement that only the external device performs LBT and initiates a communication session results from the asymmetry of a telemetry link involving an implant that has a very limited power source, has reduced antenna efficiency, and is subject to tissue attenuation.

One example of the unique requirements and constraints for implantable transceivers is shown in the Medtronic Petition for Rulemaking dated July 28, 1997 requesting creation of the MICS band. On pages 7-11, there is analysis regarding many of the above parameters resulting in a conclusion that MICS should be within the range of 250 to 450 MHz due to technical constraints, and within 402 to 405 MHz when spectrum availability is considered. Further evidence of the compatibility in requirements for human and animal implants can be inferred from the fact that Transoma has asked for no technical changes to the highly specialized MICS regulations as part of its proposal. With this compatibility, it seems reasonable to utilize the same or similar spectrum and apply the same or similar regulations as long as the two applications are non-interfering.

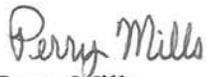
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In summary, Transoma believes that the concerns Medtronic has raised are addressed by this review and clarification of the Transoma proposal. As long as the human and animal areas of use are largely segregated, the bandwidth used by animal implants is a low percentage of the overall bandwidth, and both systems use LBT and AFA, the human and animal applications will be non-interfering. Transoma believes these conditions are met.

In view of the above and the option to make nonhuman-use secondary to human-use, Transoma believes that the necessary requirements are met to permit both uses in the band.

Respectfully submitted,



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Transoma Medical

cc. Julius Knapp, Ira Keltz, Geraldine Matise, Bruce Romano, Alan Stillwell, Jamison Prime,
and Gary Thayer