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April 16, 2015

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VIA ELECTRONIC FILING

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Room TW-A325
Washington, D.C. 20554

Re: Notice of *Ex Parte* Presentation, ET Docket Nos. 10-236 and 06-155

Dear Ms. Dortch:

On April 14, 2015, Charles Farlow, Program Director, Regulatory Affairs of Medtronic, Inc. (“Medtronic”), Nancy Victory of this firm and I met with Julius Knapp, Chief of the Office of Engineering and Technology, Ira Keltz, Deputy Chief of OET, Bruce Romano, Associate OET Chief (Legal), Geraldine Matise, Associate OET Chief (Legal) and OET staff member Rodney Small to discuss Medtronic’s Petition for Reconsideration in ET Dockets 10-236 and 06-155 concerning changes to the rules that regulate the Experimental Radio Service. Specifically, Medtronic noted the importance of full and fair eligibility of medical device manufacturers for the Medical Testing License, as well as the need for clarification of the cost reimbursement rules for clinical trials.

Medtronic expressed its support for the new Medical Testing License, which was adopted in the *Report and Order* in the above-captioned proceedings, as a mechanism for permitting more flexibility to conduct FDA-approved clinical trials of equipment before obtaining FCC equipment certification. However, currently eligibility for this license is limited to “health care facilities” and excludes traditional medical device manufacturers like Medtronic. This restricted eligibility creates substantial competitive inequity given that a number of health care facilities also are device manufacturers and operate in direct competition with device manufacturers that do not also own health care facilities.¹ As a result, a device created by a manufacturer that is also a health care facility would be eligible for operation under the Medical Testing License, while a similar device created by a traditional device manufacturer like Medtronic would require FCC authority through another type of experimental license that would not be as flexible. Such

¹ Medtronic invests over \$300 million to support clinical trials each year.

Ms. Marlene H. Dortch

April 16, 2015

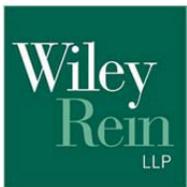
Page 2

disparate treatment of similar devices made by competing manufacturers makes no sense and would be contrary to the public interest. Accordingly, Medtronic urged that eligibility for the Medical Testing License be broadened to include all manufacturers of medical devices that can demonstrate that they are authorized by the FDA to conduct the trial, that they will have control over the devices throughout the trial (including the ability to shut off interfering devices), and that they meet other eligibility criteria necessary to demonstrate their bona fides and responsibility. To this end Medtronic proffered the attached draft language as a means of achieving the equality of eligibility called for in Medtronic's Petition for Reconsideration.

Medtronic also explained that other types of experimental licenses, such as the Conventional Experimental License and the Program Experimental License, do not offer the same flexibility to conduct clinical trials as the Medical Testing License. For example, Program Experimental Licenses may not be issued for operation on frequencies listed in Section 15.205 of the rules, which includes the 401 – 406 MHz Medical Device Radiocommunications Service ("MedRadio") band often employed by makers of implanted and body-worn medical devices.

In addition, Medtronic expressed the view that the rules for the Medical Testing License appeared to provide for greater flexibility in expanding the permissible areas of operation than do the Program Experimental Licenses and Conventional Experimental Licenses. To this end, Medtronic noted that limiting the conduct of experimental trials for devices designed to comply with Parts 15 and/or 95 of the FCC Rules to highly constrained geographic areas is impractical for testing body worn medical devices (*e.g.*, insulin pumps) and implanted devices (*e.g.*, pacemakers, defibrillators and cardiac diagnostic devices) as patients participating in clinical trials are encouraged to return to their daily lives, which includes returning home, going to work and traveling. Medtronic also pointed out that the Commission has the flexibility to insist not only that such clinical trial devices be "designed for compliance" with Part 15 and, if applicable, Part 95 as provided for in the current rules, but also that the limited number of devices used in a clinical trial be verified as compliant or that a declaration of conformity be issued for the clinical trial devices.

Finally, Medtronic discussed the need to clarify that end users may reimburse the medical device manufacturer for a portion of the costs of manufacture, research, development and handling of the investigational device consistent with FDA policy without running afoul of prohibitions in Section 2.803 and 2.805 of the



Ms. Marlene H. Dortch
April 16, 2015
Page 3

Commission's Rules. Medtronic explained that although a profit is never made on investigational devices, the charges for such a device are based on the price of a predicate device in order not to bias decisions to participate in a clinical trial on the basis of a charge or lack thereof.

Should you have any questions, please contact the undersigned counsel for Medtronic.

Respectfully submitted,

David E. Hilliard

David E. Hilliard
Counsel for Medtronic, Inc.

Attachment

cc (via email): Julius Knapp
Ira Keltz
Bruce Romano
Geraldine Matisse
Rodney Small

§5.402 Eligibility and usage.

- (a) Eligibility for medical testing licenses is limited to
- (1) health care facilities as defined in § 95.1103(b) of this chapter; or
 - (2) manufacturers of radio frequency equipment or manufacturers that integrate radio frequency equipment into their end products and meet the following requirements:
 - (i) The applicant has institutional processes to monitor and effectively manage the deployment of radiofrequency equipment in a clinical trial; and
 - (ii) The applicant has demonstrated expertise in radio spectrum management or partners with another entity that has such expertise; and
 - (iii) The trial is allowed under the rules of the United States Food and Drug Administration which authorize the applicant to conduct a clinical trial using the device to be tested.
- (b) Medical testing experimental radio licenses are for testing in clinical trials medical devices that use RF wireless technology for diagnosis, treatment, or patient monitoring for the purposes of, but not limited to, assessing patient compatibility and usage issues,...