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Via Electronic Filing

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

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

Dear Ms. Dortch,

Medtronic appreciates the efforts made by the staff of the Office of Engineering and Technology to meet Medtronic representatives on June 10, 2014, to discuss the petition for reconsideration that Medtronic submitted in this proceeding. Medtronic sought reconsideration of the Commission's decision not to include medical device manufacturers as among those eligible for medical testing experimental licenses to be used to conduct clinical trials of medical devices. Additionally, Medtronic sought clarification that the charges made in accordance with FDA rules for medical devices used in clinical testing would not run afoul of the prohibition on the marketing of devices operated under an experimental license, but which have not yet received a grant of equipment authorization. During the meeting, the Commission staff asked whether such devices are leased to participants and what disposition is made of devices.

To Medtronic's knowledge, investigational medical devices have not been leased. The devices are usually sold to the investigator at the price of a predicate device. The charge is usually passed on to the subject by the investigator¹ and does not come close to covering the research, development, manufacturing, and handling costs of the actual device provided. Thus, a medical device company does not profit on such charges. The price is set to be comparable to a predicate device in order to avoid any bias in participation based on the cost of the device to the subject.

¹ "FDA generally allows sponsors to charge investigators for investigational devices, and this cost usually is passed on to the subjects." Charging for Investigational Products - Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126427.htm> (accessed July 11, 2014).

Devices used will have been designed to comply but not certified. The final version that is FCC certified may differ in capabilities and even design from that employed in the trial (e.g., lead connectors). The medical testing license approach and the reimbursement clarification could greatly facilitate clinical trials because the limited number of devices used in such trials would not need to have first been approved in the equipment authorization process.

The investigator is responsible for investigational device distribution and tracking. An informative FDA web page² summarizes these responsibilities under 21 CFR 812 as follows:

The IDE regulations prohibit an investigator from providing an investigational device to any person not authorized to receive it [21 CFR 812.110(c)]. The best strategy for reducing the risk that an investigational device could be improperly dispensed (whether purposely or inadvertently) is for the sponsor and the investigators to closely monitor the shipping, use, and final disposal of the device(s). Upon completion or termination of a clinical investigation (or the investigator's part of an investigation), or at the sponsor's request, an investigator is required to return to the sponsor any remaining supply of the device or otherwise to dispose of the device as the sponsor directs [21 CFR 812.110(c)]. Investigators must also maintain complete, current and accurate records of the receipt, use, or disposition of investigational devices [21 CFR 812.140(a)(2)]. Specific recordkeeping requirements are set forth at 21 CFR 812.140(a).

An implanted investigational device would be explanted if in the best interest of the patient or explanted post mortem. As noted above, investigational devices, including implants, are carefully tracked to ensure that those responsible for the trial know which subject has a particular device. Implanted clinical trial devices are not intended to be reused. Medtronic urges all physicians to return explanted products and to notify Medtronic when a product is no longer in use, regardless of reason for explant or removal from use. Medtronic also requests the return of devices from non-clinical sources, such as funeral homes, and will assume responsibility for storage and disposal of the product once received.³ If a device is not implanted, arrangements are made for the return of the device upon completion of the clinical trial.

In adopting the revisions to the experimental rules, the Commission sought to facilitate the development of beneficial technology without adding undue burden for developers. Ironically, unless the reimbursement issue is clarified, the changes in the experimental licensing rules to allow for clinical trials may prove largely illusory. Similarly, without the modification of the eligibility for medical testing licenses, manufacturers of medical devices will be forced to employ a far more cumbersome process unless the manufacturer also happens to be qualify as a health care facility such as a hospital or clinic.

² Investigators' Responsibilities For Significant Risk Device Investigations (Nov. 1995), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049864.htm> (accessed July 11, 2014).

³ Medtronic CRDM Product Performance eSource "Help us improve our products" web page, http://wwwp.medtronic.com/productperformance/content/contact_us.html (accessed July 10, 2014).

Thank you for the opportunity to follow-up on the dialog in which the FCC so graciously engaged last month. If there are additional questions, please contact me.

Respectfully,

/s/ Charles S. Farlow

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