## Medtronic

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March 30th, 2018

Equipment Authorization Branch
Federal Communications Commission
Columbia. MD 21046

Subject: Confidentiality Request Letter pertaining to the certification of FCC ID No: LF5PA97000

Ladies and gentlemen,

Medtronic, Inc. ("Medtronic") requests that the information contained in the items enumerated below pertaining to the above-referenced application be withheld from public disclosure in accordance with Commission's Rules, 47 C.F.R.  $\S$  0.457(d) and 0.459, following grant of the application.

The confidential information is embodied in circuit diagrams, detailed explanations, parts lists, block diagram, and internal photographs of a device designed for patients under the care of a medical professional. As such, this material is treated as highly confidential business information and information that could convey trade secrets pertaining to manufacturing and design techniques. The information for which confidentiality is sought is employed in the design and manufacture of medical device systems that are offered on a highly competitive basis. Customers for this equipment have a variety of competing sources of supply from both domestic and foreign suppliers. Disclosure would, in effect, give away the fruits of the labors of Medtronic's engineering personnel, who have designed the equipment and the manufacturing processes. Disclosure would also offer competitors additional unwarranted insight into the state of product development thereby allowing such competitors an advantage that would not be available to Medtronic.

The information for which confidential treatment is sought is kept confidential by Medtronic and not made available to third parties except pursuant to arrangements designed to prevent public disclosure (Non-Disclosure Agreements, of which an example is attached to this letter). To the knowledge of those preparing this application, the information has not been disclosed publicly heretofore. The protection sought is narrowly drawn and pertains to certain specific implementations of the technology incorporated into the device for which certification is sought.

## Long-Term Confidentiality

The materials set forth in the following exhibits, which are segregated from the non-confidential exhibits of the application, are the ones for which Medtronic requests **Long-Term Confidentiality**:

- Internal Photos
- Schematics
- Block Diagram
- Theory of Operation / Operational description
- Parts list / Tune Up Info

Following the Equipment Authorization Confidentiality Request Procedures as described in KDB Guidance 726920 D01 of April 8<sup>th</sup> 2016, Internal Photos may be held Long-Term Confidential under the condition that the circuit board or internal components are not accessible to users.

Medtronic's PA97000 model, which is the subject of this future filing, is not available to the public. The devices are regulated by the FDA and are available by prescription only by health care professionals and used with devices that are implanted directly in the patient. To avoid opening, the model is constructed in a manner that it cannot be easily opened and the Instructions for Use specify that the device should not be opened. Therefore, the equipment to which this Long-Term Confidentiality request pertains satisfies this criterion.

## **Short-Term Confidentiality**

The materials set forth in the following exhibits, which are also segregated from the non-confidential exhibits of the application, are the ones for which Medtronic requests **Short-Term Confidentiality** for a period of 180 days from the date of the grant:

- External Photos
- Test Setup Photos
- User Manuals

User manuals will be published online at the time of market release and will not be disclosed to the end user prior to marketing.

Respectfully,

Christiaan Masson

Masson

Regulatory Affairs Program Manager

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