Medtronic, Inc
Cheryl Swanson
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K190574
Trade/Device Name: Patient Assistant Model PA97000
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: August 21, 2019
Received: August 22, 2019

Dear Cheryl Swanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole Goodsell
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190574

Device Name
Patient Assistant Model 97000

Indications for Use *(Describe)*
The Patient Assistant model PA97000 initiates the recording of cardiac event data in the device memory of a Medtronic insertable cardiac monitor. The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

The following table provides background information regarding this Traditional 510(k) submission:

Date Prepared:	March 1, 2019
510(k) Owner / Address:	Medtronic, Inc. Cardiac Rhythm and Heart Failure 8200 Coral Sea Street NE Mounds View, MN 55112
Contact Person:	Cheryl Swanson Senior Principal Regulatory Affairs Specialist cheryl.swanson@medtronic.com Office: (763) 514-0088 Cell: (651) 242-3506 Secondary Contact: Ryan Calabrese Senior Regulatory Affairs Director ryan.s.calabrese@medtronic.com Office: (763) 526-3515
Submission Type:	Traditional 510(k)
Device Trade Name:	Patient Assistant, Model 97000
Device Common Name:	Patient Assistant
Product Code and Classification Regulation Name:	DSI: Arrhythmia Detector and Alarm 21 CFR 870.1025 Class II
Predicate Devices:	K150177

Device Description

The PA97000 Patient Assistant (hereinafter referred to as PA97000) is a hand-held, battery operated, Bluetooth Low Energy (BLE) device used by patients to mark symptoms in the memory of their implantable device, as illustrated in **Figure 1: Image of PA97000**. It is intended for unsupervised use away from a hospital or clinic.

Figure 1: Image of PA97000

Device Purpose

The PA97000 Patient Assistant provides three key functions for the user:

1. Activates the data management feature in an insertable cardiac device to initiate recording of cardiac event data in the implanted device memory. The stored episodes are used by the clinician to correlate the patient's cardiac rhythm with their symptoms.
2. Provides feedback to the user that the PA97000 is searching for the implanted device.
3. Provides feedback to the user that the PA97000 has marked a symptom in the implanted device memory.

Indications for Use

The Patient Assistant model PA97000 initiates the recording of cardiac event data in the device memory of an Insertable Cardiac Monitor. The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic.

Summary of Changes

The primary changes from the Patient Assistant Model PA96000 to the PA97000 are as follows:

1. Update the communication protocol from Telemetry B to Bluetooth Low Energy (BTLE)
2. Update the Indications for Use to state the PA97000 can be used with the an Insertable Cardiac Monitor that the subject device is tested with.

Technological Characteristics

The PA97000 operates identically to the PA96000. The only difference is the communication protocol used by PA97000 is Bluetooth LE rather than Telemetry B that is used by the predicate device. Analysis of the change confirms it does not raise new questions of safety or effectiveness. This conclusion is supported by a thorough hazard analysis and extensive testing.

Summary of Testing and Performance Data

The proposed changes to the PA97000 were fully verified and validated in accordance with design control requirements. Device verification testing was performed to demonstrate the

PA97000 meets established performance criteria and supports substantial equivalency to the Patient Assistant Model PA96000.

The following performance data were provided in support of the substantial equivalence determination.

- Safety Design Verification
- EMC Design Verification
- Environmental Design Verification
- Mechanical Design Verification
- Firmware Design Verification
- Packaging Design Verification
- Security Design Validation
- System Design Validation
- Human Factors Testing
- Biocompatibility

Conclusion

The intended use, design, materials and performance of the PA97000 are substantially equivalent to the predicate Patient Assistant Model PA96000. This is supported by a thorough hazard analysis and extensive testing.