DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2015

Medtronic, Inc.
c/o Mr. Eric Kalmes
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K150117
Trade/Device Name: Patient Assistant Model PA96000
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class II
Product Code: DSI
Dated: April 21, 2015
Received: April 22, 2015

Dear Mr. Kalmes:

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. 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.

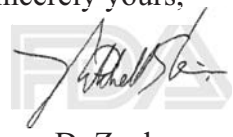
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150117

Device Name
Patient Assistant Model PA96000

Indications for Use *(Describe)*

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic.
The Patient Assistant activates the data management features in the Reveal Family of Insertable Cardiac Monitors (ICM) to initiate recording of cardiac event data in the implanted device memory.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary Complying with 21 CFR 807.92

Date Prepared:	05 February 2015
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
Contact:	Eric Kalmes Principal Regulatory Affairs Specialist
Telephone:	(763)526-2809
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E-mail:	eric.b.kalmes@medtronic.com
Proprietary Name:	Patient Assistant, Model PA96000
Common Name:	Patient Assistant
Device Classification	Class II, 21 CFR 870.1025, Arrhythmia detector and alarm
Product Code:	DSI
Device Predicate:	Patient Assistant Model 9538 – 510(k) **K103764**

Summary of Substantial Equivalence and Predicate Device

The intended use, design, materials and performance of the Medtronic Patient Assistant (Model PA96000) are substantially equivalent to the predicate device Patient Assistant Model 9538 (510(k) K103764). This predicate has not been subject to a design-related recall.

Device Description

The Patient Assistant is a handheld, battery-operated, radio-frequency device used to communicate with the Reveal Insertable Cardiac Monitors. It utilizes Medtronic's Telemetry B protocol for communication. The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor. The Patient Assistant's function is to mark symptomatic episodes in the implanted device memory.

Figure 1: Patient Assistant

Summary of changes

Changes were made to the new PA96000 increase patient acceptance by reducing size, improving form factor, and eliminating the need for replaceable batteries.

- Reduced size and form factor to allow patients to more easily carry with them.
- New visual indicator for successful marking of symptom allows confirmation on marking symptoms in addition to the audio tone.
- Non-replaceable battery and no end of life indicator. The Patient Assistant is being designed with sufficient battery capacity to support the entire life of the device. Given the expected use conditions, battery replacements will not be necessary. Batteries are non-replaceable (no removable battery compartment) because the device's longevity is as long or longer as the Reveal implantable and simplifies patient ease of use.

Indications for Use

There are no changes to the Indications for Use. The Indications for Use are provided below:

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management features in the Reveal Family of Insertable Cardiac Monitors (ICM) to initiate recording of cardiac event data in the implanted device memory.

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate device referenced. There are no differences between the subject and predicate devices.

Summary of Testing and Performance data

All of the proposed changes to the subject Patient Assistant Model PA96000 were fully verified and validated in accordance with design control requirements. Device verification testing was

performed to demonstrate the Patient Assistant Model PA96000 meet established performance criteria to support equivalency to the reference predicate device.

The results of the testing indicate that the Medtronic Patient Assistant performs as intended and is safe for its intended use.

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

- **Hardware Verification Testing** - All tests and reviews were executed per the test plan, with no deviations. The results provide verification evidence that requirements in PA96000 Hardware Requirements Specification met the acceptance criteria as set per those requirements.
- **Firmware Verification Testing** -
    - Software Level of Concern based on the product Risk Analysis, which includes hardware and software components, the associated hazards and corrective action, the guidance document *Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm* dated October 28, 2003, and the guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005, Medtronic concludes the Patient Assistant Model PA96000 software represents a major level of concern. In accordance all documentation was submitted based on level of concern**.**
    - All firmware testing for the PA96000 Patient Assistant was successfully completed. The analysis and testing performed demonstrates the firmware as identified operates per specification.
- **Mechanical Design Verification Testing** - Mechanical Design Verification has been completed showing the product design output meets its design input requirements. These tests were created based on PA96000 Mechanical Requirements Specification. There were no deviations from the Mechanical Design Verification Plan. There were no test issues encountered. All testing was completed and passed.
- **Environmental Verification Testing** - The testing performed demonstrates the PA96000 meets its environmental requirements as described in the PA96000 Environmental Verification Test Plan.
- **Human Factors Testing** - Human factors Engineering Validation Study of the Patient Assistant (model PA96000) was conducted. The 20 participants recruited and tested in the study were representative of current ICM patients. 100% of the participants completed the study tasks without any use errors that could result in a hazardous outcome.
    - Participant performance did not reveal any new use errors that could result in a hazardous outcome.
    - In addition, 90% of representative users with appropriate training were able to mark a symptomatic event with the Patient Assistant.
    - Based upon the analysis of the priori goals, the Patient assistant (model PA96000) is deemed safe and effective for use

- **Biocompatibility Testing** - A biological evaluation as guided by the applicable sections of ISO 10993-1:2009/AC: 2010 that pertain to biological effects has been performed for the Patient Assistant PA96000. This evaluation describes the patient contact of the device and the available biological safety information. This biological evaluation report demonstrates the biological safety of the PA96000 Patient Assistant.
- **Packaging Verification Testing** - Package system performance testing was performed according to ASTM D-4169, Assurance Level 1, and Distribution Cycle 13. The PA96000 Patient Assistant product packaging as outlined in the Package Design Verification Plan, DSN015024, passed all aspects of the package testing and is acceptable for use as intended.
- **System Validation** - System Validation testing for the PA96000 Patient Assistant project was successfully completed. The analysis and testing performed demonstrates the PA96000 operates per the Design Input Requirement Specification

Guidance used to Demonstrate Substantial Equivalence

Guidance documents used/considered for these device modifications include, but are not limited to, the following:

- Draft Guidance Document titled *Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, issued on April 23, 2013
- Draft Guidance Document titled Design Considerations for Devices Intended for Home Use, issued December 12, 2012
- Radio Frequency Wireless Technology in Medical Devices, issued on August 14, 2013
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005
- *Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm* dated October 28, 2003

Standards used to Demonstrate Substantial Equivalence

The following standards were used to demonstrate substantial equivalence:

	Standard	**FDA Recognition No.**	**Summary/Trace Report**
1	EN 55011 (CISPR11) EMI Emissions Characteristics		EMC test report
2	ASTM D4169 – 09 Standard Practice for Performance Testing of Shipping Containers and Systems	14-300	LINQ PA96000 Patient Assistant Package Test Design Verification Test Report
3	EN 45502-1:1997 Active Implantable Medical Devices Part 1: General Requirements for Safety, Marking and Information to be Provided by the Manufacturer		Package and Device Labeling

	Standard	FDA Recognition No.	Summary/Trace Report
	Shall comply to Clause 5.1 only		
4	EN ISO 60601-1:2006 / A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	5-4	LINQ PA96000 Patient Assistant Environmental Verification Design Verification Test Report
5	IEC 60601-1-2:2014 Class B Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility	5-34	EMC test report
6	EN ISO 60601-1-11 2010 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance —Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	19-6	LINQ PA96000 Patient Assistant Environmental Verification Design Verification Test Report
7	BS EN ISO 14971:2012 Medical Devices. Application of risk management to medical devices	5-40	Summary Risk Management Report
8	EN 1041:2008 Information supplied by the manufacturer of medical devices		IFU Design Input Requirements
9	EN 980:2008 Symbols for use in the labeling of medical devices		IFU Design Input Requirements
10	EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements - CORR: July 31, 2012	5-91	IFU Design Input Requirements
11	EN ISO 60601-1-6 2010 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	5-85	LINQ PA96000 Patient Assistant Human Factors Engineering Validation Report
12	ETSI EN 301 489-31 V1.1.1:2005 Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)		EMC testing Report

	Standard	FDA Recognition No.	Summary/Trace Report
13	EN 302 195-2 V1.1.1:2004 Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-Ami) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive		EMC testing Report
14	ISO 1000:1992 SI units and recommendations for the use of their multiples and of certain other units		IFU Design Input Requirements
15	ISO 14708-1:2000 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer		Package and Device Labeling
16	ISO 80000-1:2009 Quantities and units - Part 1: General - Technical Corrigendum 1		IFU Design Input Requirements
17	ISO 8601:2004 Data elements and interchange formats – Information interchange – Representation of dates and times		IFU Design Input Requirements
18	EN ISO 10993-1:2009/AC:2010 Biological Evaluation of Medical Devices P1 Evaluation and Testing with a Risk Management Process	2-156	Biological Evaluation
19	JBD No. 185: 2001 National Agency of Sanitary Surveillance Decision - JBD No. 185, from the 22nd of October, 2001		IFU Design Input Requirements

Conclusion

Medtronic has demonstrated that the Patient Assistant described in this submission results in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate device. We have provided summary data to demonstrate reasonable assurance of safety and effectiveness of the subject Patient Assistant PA96000 and to demonstrate substantial equivalence to its predicate. As supported by the descriptive information, verification, validation and standards testing, the modified patient assistant is as safe and effective, and performs as well as or better than the predicate device.