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

March 30, 2016

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

Re: K153160
Trade/Device Name: AVIVO™ Mobile Patient Management (MPM) System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSB, DSI
Dated: February 29, 2016
Received: March 1, 2016

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. 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.

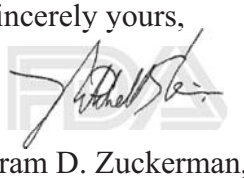
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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)*
K153160

Device Name
AVIVO™ ® Mobile Patient Management (MPM) System

Indications for Use *(Describe)*
The AVIVO™ Mobile Patient Management (MPM) System is intended to continuously measure, record and periodically transmit physiological data. The AVIVO™ MPM System is indicated for patients:
• With fluid management problems
• Taking diuretic medication
• Living with heart failure
• Living with end-stage renal disease
• Suffering from recurrent dehydration
• Who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders.

The AVIVO™ MPM System monitors, derives and displays:
• ECG
• Heart Rate (including HR variability)
• Activity
• Posture
• Respiration Rate (including RR variability)
• Body Fluid Status

The system has not been tested specifically for pediatric use.

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.

510(k) SUMMARY

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

Date Prepared:	October 30, 2015
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 Regulatory Affairs Director ryan.s.calabrese@medtronic.com Office: 763-526-3515
Submission Type:	Special 510(k): Device Modification
Device Trade Name:	AVIVO™ Mobile Patient Management (MPM) System
Device Common Name:	Mobile Patient Management (MPM) System
Product Code and Classification Regulation Name:	DSB: Plethysmograph, Impedence DSI: Detector and Alarm, Arrhythmia MHX: Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
Predicate Devices:	**Primary** K113187, cleared January 4, 2012 (AVIVO™ MPM) **Secondary** K113372, cleared March 7, 2012 (NUVANT™ MCT) K133701, cleared February 6, 2014 (NUVANT™ MCT) - **rebranded as SEEQ™ MCT**

Device Description

The AVIVO™ MPM System is a wearable, wireless physiological monitoring and arrhythmia detection system that is used by patients to aid clinicians in the identification, diagnosis and management of various clinical conditions, events and/or trends. It consists primarily of the Wearable Sensor (monitoring device) and the Transmitter (portable data transmission device). In combination with interpretation services provided by Medtronic Monitoring, Inc.'s Monitoring Center, as well as secure online review of data by healthcare providers, the AVIVO™ MPM System enables patient- and physician-friendly physiological monitoring and arrhythmia detection for extended periods of time.

Significant Physical and Performance Characteristics of the Device

The AVIVO™ MPM System is comprised of the following non-sterile components:

- The Wearable Sensor, which adheres to the patient's torso, contains electrodes and sensors for recording patient information.
- The Transmitter, which is the patient hand-held transceiver, receives information from the Wearable Sensor and transmits it to the Medtronic Server.
- The secure Server, which receives information from the Wearable Sensor via the Transmitter, and among other things, derives, calculates and displays the patient's physiological parameters using the data collected by the Wearable Sensor.

This remains unchanged from the predicate device.

Indications for Use Statement

The AVIVO™ Mobile Patient Management (MPM) System is intended to continuously measure, record and periodically transmit physiological data. The AVIVO™ MPM System is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Living with end-stage renal disease
- Suffering from recurrent dehydration
- Who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders.

The AVIVO™ MPM System monitors, derives and displays:

- ECG
- Heart Rate (including HR variability)
- Activity
- Posture

- Respiration Rate (including RR variability)
- Body Fluid Status

The system has not been tested specifically for pediatric use.

Intended Use of the Device

The AVIVO™ MPM System is intended for the ambulatory recording and monitoring of physiological parameter(s).

This remains unchanged from the predicate device.

Comparison of Fundamental Scientific Technology with the Predicate Devices

The subject AVIVO™ MPM System operates the same as the predicates, based on the following fundamental scientific technology:

- The collection of physiological parameters by a multi-sensor patient-worn device (Wearable Sensor);
- The transmission of these parameters to a remote Server through a transceiver (Transmitter); and
- The receipt of the parameters by the Server and subsequent derivation into appropriate useful values for display.

This remains unchanged from the predicate device.

Summary of Testing and Performance Data to Demonstrate Substantial Equivalence

The AVIVO™ MPM System is supported by the successful completion of the following tests to demonstrate substantial equivalence.

Table 4: Summary of Completed Testing to Support this Submission

Section Description	Modification 1	Modification 2	Modification 3
Sterilization and Shelf Life	N/A – no changes to sterilization or shelf life related to this modification	Testing for this change already provided in K133701	N/A – no changes to sterilization or shelf life related to this modification
Biocompatibility	N/A – no changes to biocompatibility related to this modification	Although there were no changes to the patient-contacting materials related to this modification, biocompatibility testing was repeated	N/A – no changes to biocompatibility related to this modification

Section Description	Modification 1	Modification 2	Modification 3
		and results provided in K133701	
Software	Testing for this modification already provided in K113372	Testing for this modification already provided in K133701	Discussed in the **Software Section**
EMC Testing	N/A – no EMC changes associated with this modification	Testing for this modification already provided in K133701	N/A – no EMC changes associated with this modification
Performance Testing – Bench **Mechanical** **Electrical**	N/A – no mechanical or electrical changes associated with this modification	Testing for this change already provided in K133701	N/A– no mechanical or electrical changes associated with this modification
Performance Testing – Animal	N/A – no animal testing required for this modification	N/A – no animal testing required for this modification	N/A – no animal testing required for this modification
Performance Testing – Clinical	N/A – no clinical testing required for this modification	N/A – no clinical testing required for this modification	N/A – no clinical testing required for this modification
Cybersecurity	N/A – no cybersecurity changes associated with this modification	N/A – no cybersecurity changes associated with this modification	N/A – no cybersecurity changes associated with this modification. Note: This section is included due to the release of the final FDA guidance document since the last submission. See the **Cybersecurity Section** for details.
RF & Wireless Technology	N/A – no RF & Wireless changes associated with this modification.	N/A – no RF or Wireless changes associated with this modification. Note: following this submission, the Transmitter's cellular technology was updated. As such, RF & Wireless	N/A – no RF & Wireless changes associated with this modification.

Section Description	Modification 1	Modification 2	Modification 3
		Technology is discussed in the **RF & Wireless Technology Section**	

System validation testing was also successfully completed to demonstrate that the modified AVIVO™ MPM System functions as expected and that the system meets user needs and intended use.

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
- Design Considerations for Devices Intended for Home Use, issued on November 24, 2014
- Radio Frequency Wireless Technology in Medical Devices, issued on August 13, 2013
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued on October 2, 2014
- 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

Table 5 identifies the standards that were also used, in whole or in part, to demonstrate substantial equivalence:

Table 5: Standards to Demonstrate Substantial Equivalence

Standards Organization / Number	Standards Title	Date / Version
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005 + CORR 1 (2006) + CORR 2 (2007) / 3rd Edition

Standards Organization / Number	Standards Title	Date / Version
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2007 / 3rd Edition
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability	2010-01 / 3rd Edition
IEC 60601-1-11	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	2010-04 / 1st Edition
ANSI/AAMI/IEC 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the safety and essential performance of ambulatory electrocardiographic systems	2012 / 2nd Edition
ANSI/AAMI/IEC 62304	Medical Device Software – Software life cycle processes (Edition 1)	2006-005
AAMI/ANSI EC 12	Disposable ECG electrodes	2000 (R) 2010
AAMI/ANSI EC 57	Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms	2012
AAMI/ANSI/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009

Standards Organization / Number	Standards Title	Date / Version
AAMI/ANSI/ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	2009
AAMI/ANSI/ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	2010
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices (Edition 2)	2007-03-01; 2012

Conclusion

Medtronic has demonstrated that the AVIVO™ MPM System, as described in this submission, results in a substantially equivalent device because the fundamental scientific technology, operating principles and intended use are unchanged from the predicate devices. Summary data has been provided to demonstrate reasonable assurance of safety and effectiveness of the AVIVO™ MPM System and to demonstrate substantial equivalence to its predicates. As supported by the descriptive information, verification, validation and standards testing, the modified AVIVO™ MPM System is substantially equivalent to the predicate devices.