DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 6, 2016

Medtronic, Inc.
Heather Taylor
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mail Stop MVS46
Mounds View, Minnesota 55112

Re: K153139
Trade/Device Name: Achieve ST Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: April 5, 2016
Received: April 6, 2016

Dear Heather Taylor:

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)*
K153139

Device Name
AchieveTM ST Mapping Catheter

Indications for Use *(Describe)*
The AchieveTM ST mapping catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The AchieveTM ST mapping catheter is designed to obtain electrograms in the atrial regions of the heart.

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.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared: October 26, 2015

Applicant:
Medtronic Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

Establishment Registration No.: 3001504994

Contact Person:
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Coral Sea Street
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Trade Name: Achieve™ ST Mapping Catheter

Common Name: Catheter, electrode recording, or probe, electrode recording

Classification Name: Electrode Recording Catheter

Classification & Panel: Class II, 21 CFR 870.1220

Product Code: DRF

Predicate Device(s): Achieve™ Mapping Catheter K102588

Device Description: The Achieve ST Mapping diagnostic catheter is an intra-cardiac electrophysiology recording catheter and can be used for cardiac stimulation during electrophysiology studies. The distal mapping section of the Achieve ST Mapping Catheter is a circular loop with evenly spaced electrodes to map electrical conduction within the atrium. The Achieve ST Mapping Catheter is available in a 25mm pre-shaped distal loop diameter.

Intended Use of Device: The intended use of the Achieve ST Mapping Catheter is to record

intracardiac signals and provide cardiac stimulation during electrophysiology studies.

The Achieve ST mapping catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Achieve ST mapping catheter is designed to obtain electrograms in the atrial regions of the heart.

Comparison of Technological Characteristics

The Achieve ST Mapping Catheter uses similar technology, has similar intended use, functions, materials and method of operation as the following predicated device:

	Achieve ST Catheter (Subject Device) K153139	Achieve Catheter (predicate device) K102588
Intended Use	Map intracardiac structures of the heart	Map intracardiac structures of the heart
Indications for Use	The Achieve ST is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Achieve ST Catheter is designed to obtain electrograms in the atrial regions of the heart.	The Achieve is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Achieve Catheter is designed to obtain electrograms in the atrial regions of the heart.
Catheter Body Tubing	Pebax (distal body) Stainless Steel/ polyimide (proximal)	Pebax (distal body) Stainless Steel (proximal)
Diameter	3.3F	3.3F
Effective Length	146cm	146cm
Number of Electrodes	10	8
Distal End Shape	Circular Loop	Circular Loop
Loop Diameter	25mm	15mm and 20mm
Loop Material	Nitinol insulated	Nitinol insulated with

	with PET (Pebax covered)	PET (Pebax covered)
Delivered through a delivery catheter	Yes	Yes

Performance Data

In vitro bench testing and *in vivo* testing have been performed on the device materials and finished devices. Performance, sterilization and biocompatibility testing verified that the Achieve ST Mapping Catheter performs as designed and is suitable for its intended use.

Performance testing included the following:
Radial Loop Compliance
Distal Stiffness
Axial Load
Torque Response
Turns to Failure
Electrical Continuity
Device Functionality
Kink Resistance
Joint Strength
Contrast Media Flow Rate
Stiffness
Electrical Testing and Electrical Safety Testing (ISO 60601-1:2006)
Corrosion Resistance (ISO 10555-1:2009)

Biocompatability testing included the following:
Cytotoxicity (ISO 10993-5)
Kligman Sensitization (ISO 10993-10)
Intracutaneous Injection (ISO 10993-10)
Systemic Injection, Acute (ISO 10993-11)
Rabbit Pyrogen, Material Mediated (ISO 10993-11)
Hemolysis (ASTM F756)
Prothombin Time Assay (ISO 10993-4)
Unactivated Partial Thromboplast in Time Assay (ISO 10993-4)
Complement Activation Assay (ISO 10993-4)
Thrombogenicity (ISO 10993-4)

The associated Connecting Cable has been tested and is considered safe and effective per applicable parts of BS EN 60601-1 (2006, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance).

Conclusion	The data presented in this submission demonstrate that the Achieve ST Mapping Catheter is substantially equivalent to the predicate device identified in regards to device design, materials, and intended use.