April 19, 2018

Medtronic, Inc.
Brenna Loufek
Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K180873
Trade/Device Name: Medtronic Model 53401 External Pulse Generator (EPG)
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class II
Product Code: DTE
Dated: April 2, 2018
Received: April 3, 2018

Dear Brenna Loufek:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180873

Device Name
Medtronic Model 53401 External Pulse Generator (EPG)

Indications for Use *(Describe)*

The Medtronic Temporary External Pacemaker 53401 is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. It can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic, or diagnostic purposes.

Specific indications for temporary cardiac pacing include, but are not limited to, the following indications:

- Complete heart block
- Sinus bradycardia
- Sick Sinus Syndrome
- Bradycardia with congestive heart failure
- Atrial and/or ventricular arrhythmias
- Cardiac arrest
- Temporary support, management, and evaluation of a patient prior to permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Temporary support of a patient following cardiac surgery
- Acute myocardial infarction complicated by heart block
- High-rate burst pacing for the treatment of supraventricular tachyarrhythmias

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

[As required by 21 CFR 807.92]

Date Prepared: March 16, 2018

Submitter: Medtronic, Inc.
Medtronic Cardiac Rhythm Heart Failure
8200 Coral Sea Street N.E.
Mounds View, MN 55112
Establishment Registration Number: 2182208

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General Information

Trade Name: Medtronic Model 53401 External Pulse Generator (EPG)

Common Name: External pacemaker pulse generator

Regulation Number: 21 CFR 870.3600

Product Code: DTE

Classification: Class II

Classification Panel: Cardiovascular

Special Controls: Not applicable

Predicate Devices: **Medtronic Model 53401 External Pulse Generator (EPG) K162054**

Device Description

The Medtronic Temporary External Pacemaker Model 53401 (hereafter simply referred to as the 53401; or the 53401 SC EPG where SC EPG stands for Single Chamber External Pulse Generator) is a battery-powered, single chamber, temporary pacemaker designed primarily for temporary antibradycardia pacing therapy. The Model 53408 is an optional disposable protective cover to reduce accidental activation of the controls of the 53401 SC EPG.

Indications for Use

The Medtronic Temporary External Pacemaker 53401 is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. It can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic, or diagnostic purposes.

Specific indications for temporary cardiac pacing include, but are not limited to, the following indications:

- Complete heart block
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- Bradycardia with congestive heart failure
- Atrial and/or ventricular arrhythmias
- Cardiac arrest
- Temporary support, management, and evaluation of a patient prior to permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Temporary support of a patient following cardiac surgery
- Acute myocardial infarction complicated by heart block
- High-rate burst pacing for the treatment of supraventricular tachyarrhythmias

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate devices referenced.

When compared to the predicate device (K162054), the modified Medtronic Model 53401 External Pulse Generator presented in this submission has the same:

- Intended use/indications for use
- Operating principle
- Design features
- Device functionality

- Biological safety
- Packaging materials
- Shelf life

The modified Model 53401 EPG and the predicate device differ in the following:

- The modified 53401 EPG has updated firmware, Firmware Version 1.03

Substantial Equivalence and Summary of Studies:

Technological differences between the subject and predicate devices have been evaluated with firmware design verification and system verification. The data from the newly verified firmware show that the devices could be manufactured with a new firmware version to mitigate rebooting of the device caused by interrupts in the firmware system.

The modified Medtronic Model 53401 External Pulse Generator is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design and materials have been verified through the following:

- Firmware Verification
- System Verification

Conclusion:

The results of the above verification testing met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the modifications made to the Medtronic Model 53401 External Pulse Generator described in this submission result in a device that is substantially equivalent to the predicate.