



April 30, 2019

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

Re: K190825

Trade/Device Name: Medtronic Model 5392 External Pulse Generator (EPG)
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class III
Product Code: DTE
Dated: March 29, 2019
Received: April 1, 2019

Dear Alexandra Theisen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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

Indications for Use

510(k) Number (if known)
K190825

Device Name

Medtronic Temporary External Pacemaker 5392

Indications for Use (Describe)

The temporary pacemaker is used with a cardiac pacing lead system for temporary single or dual chamber pacing in a clinical environment by trained personnel. The temporary pacemaker can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic or diagnostic purposes. The temporary pacemaker must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient.

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

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Atrial and/or ventricular arrhythmias
- Cardiac arrest
- Support, management, and evaluation of a patient prior to permanent pacemaker Implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Support following cardiac surgery
- Acute myocardial infarction complicated by heart block
- Atrial tachyarrhythmias that require high-rate burst pacing for treatment

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: March 29, 2019

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

Contact Person: Alexandra Theisen
Regulatory Affairs Specialist
Medtronic Cardiac Rhythm Heart Failure
Phone: 763.526.6758
Fax: 651.367.0603
Email: alexandra.r.theisen@medtronic.com

Alternate Contact: Rachel Libi
Senior Regulatory Affairs Manager
Medtronic Cardiac Rhythm Heart Failure
Phone: 763.526.1668
Fax: 651.367.0603
Email: rachel.libi@medtronic.com

General Information

Trade Name: Medtronic Model 5392 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 5392 External Pulse Generator (EPG) K181973

Device Description

The Model 5392 EPG is a battery-powered, dual chamber, temporary pacemaker designed primarily for temporary antibradycardia pacing therapy. The 53922 EPG cover accessory is an optional disposable protective cover to reduce accidental activation of the controls of the 5392 EPG.

Indications for Use

The temporary pacemaker is used with a cardiac pacing lead system for temporary single or dual chamber pacing in a clinical environment by trained personnel. The temporary pacemaker can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic or diagnostic purposes. The temporary pacemaker must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient.

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

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Atrial and/or ventricular arrhythmias
- Cardiac arrest
- Support, management, and evaluation of a patient prior to permanent pacemaker Implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Support following cardiac surgery
- Acute myocardial infarction complicated by heart block
- Atrial tachyarrhythmias that require high-rate burst pacing for treatment

Technological Characteristics

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

When compared to the predicate device (K181973), the modified Medtronic Model 5392 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 5392 EPG and the predicate device differ in the following:

- Modified patient connector material

Substantial Equivalence and Summary of Studies:

Technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence of safe and effective use. The data from this testing showed that the devices could be manufactured with the modified patient connector material and continue to meet the current 5392 design specifications.

The modified Medtronic Model 5392 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:

- Regression bench testing

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 5392 External Pulse Generator described in this submission result in a device that is substantially equivalent to the predicate.