



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

October 12, 2016

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

Re: K162550

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 II
Product Code: DTE
Dated: September 12, 2016
Received: September 13, 2016

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.

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

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)
K162550

Device Name
Medtronic Model 5392 External Pulse Generator (EPG)

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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: October 11, 2016

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 5392 External Pulse Generator (EPG)

Common Name: External pacemaker pulse generator

Regulation Number: 21 CFR 870.3600

Product Code: DTE

Classification: Class II (As per Final Order published 18-APR-2016 by FDA docket number 2011-N-0650)

Classification Panel: Cardiovascular

Special Controls: Not applicable

Predicate Devices: **Medtronic Model 5392 External Pulse Generator (EPG) K150246**

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
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- 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.

Technological Characteristics

When compared to the predicate device (K150246), 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 routing and length of three internal cables

Substantial Equivalence and Summary of Studies:

Technological differences between the subject and predicate devices have been evaluated with devices manufactured with the updated cables and new routing. The data from the newly qualified process shows that the devices could be manufactured with minor enhancements to the design specifications to mitigate internal pinching of the Patient Cable, Battery Cable, and LCD Cable.

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:

- Qualification of the manufacturing process, including new fixtures

Conclusion:

The results of the above qualification 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.