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

October 18, 2016

Medtronic, Inc.
Syed Mohiuddin
Principal Regulatory Affairs Specialist
8200 Coral Sea Street Ne
Mounds View, Minnesota 55112

Re: K162054
Trade/Device Name: Medtronic Temporary External Pacemaker 53401
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class II
Product Code: DTE
Dated: July 22, 2016
Received: July 25, 2016

Dear Syed Mohiuddin:

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,

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)*
K162054

Device Name
Medtronic Temporary External Pacemaker 53401

Indications for Use *(Describe)*
The Model 53401 SC EPG is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. The device can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylatic, or diagnostic purposes.

Specification 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

Introduction

Medtronic is submitting this Traditional 510(k) to establish substantial equivalence of the Temporary External Pacemaker Model 53401 to its legally marketed predicate device. The Table 3 below lists the administrative information related to this 510(k) submission.

Table 3: 510(k) Summary

510(k) Administrative Information	
Date Prepared:	20 July 2016
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
Contact:	Syed Sumran Mohiuddin Principal Regulatory Affairs Specialist
Telephone:	(763)526-2380
Fax:	(651)367-0603
E-mail:	syed.s.mohiuddin@medtronic.com
Proprietary Name:	Medtronic Temporary External Pacemaker Model 53401
Common Name:	External pacemaker pulse generator
Device Classification	Class II (special controls), 21 CFR 870.3600 External pacemaker pulse generator
Product Code:	DTE

Substantial Equivalence Statement

The intended use, design, materials and performance of the Medtronic Temporary External Pacemaker Model 53401 is substantially equivalent to the following predicate device:

- Medtronic Model 5392 Dual Chamber Temporary External Pacemaker, initially cleared via 510(k) application, reference number K132924 on October 31, 2013.

Brief 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 53401 SC EPG is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. The 53401can 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

Technological Characteristics

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

Overview of Testing

Design verification and validation was performed to demonstrate that the Medtronic 53401 SC EPG and its accessories meet established performance criteria to support equivalency to the referenced predicate device. Draft Guidance − Class II Special Controls Guidance Document: External Pacemaker Pulse Generator was followed. All performance testing conducted was non-clinical, and consisted of bench testing and human factors evaluation testing. The testing results indicate that the 53401 SC EPG performs as intended.

The Table 4 below lists the performance standards that were used during testing:

Table 4: Standards & Testing

No.	Standard	Summary/Trace Report
1	IEC 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for safety	UL Test Reports, NW EMC Reports, and Product Verification
2	IEC 60601-1-2: 2014 Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	
3	IEC 60601-2-31: 2011 1995 Particular Requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	
4	IEC 60601-1-6:2013 General requirements for basic safety and essential performance – Collateral standard: Usability from the International Electrotechnical Commission	
5	EN 62366:2014 Medical devices -- Application of usability engineering to medical devices from the International Electrotechnical Commission	Human Factors Evaluation
6	ISO 10993-1:2013 Biological Evaluation of Medical Devices	Biocompatibility Testing
7	IEC EN 62304: 2006/AC:2008 Medical device software - Software life-cycle processes	Firmware (Embedded Software) Verification and Validation
8	ASTM D4169: 2008 Practice for performance testing of shipping containers and systems	Packaging Testing
9	ANSI/AAMI HE75: 2013 Human factors design process for medical devices from the Association for the Advancement of Medical Instrumentation	Human Factors Evaluation

Conclusion

Medtronic demonstrates in this submission that the 53401 SC EPG is substantially equivalent to its predicate device (the Model 5392 Dual Chamber Temporary External Pacemaker) because the fundamental scientific principle, operating principle, design features and intended use are substantially equivalent to the predicate device.