July 12, 2021

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

Re: K203556
Trade/Device Name: Medtronic Model 5492A, 5492V, 5492AL, 5492VL Patient Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: June 14, 2021
Received: June 15, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*

K203556

Device Name

Medtronic Model 5492A, 5492V, 5492AL, 5492VL Patient Cables

Indications for Use *(Describe)*

The Medtronic Model 5492A, 5492V, 5492AL, 5492VL patient cables are intended for use as part of a temporary cardiac pacing system. They connect atrial and ventricular pacing lead systems to a temporary external pacemaker. They are intended for use by trained clinicians in a clinical environment. For more information about the intended use of and the indications for temporary cardiac pacing systems, refer to the technical manuals for the cardiovascular stimulating instruments.

The Model 5492A, 5492V, 5492AL, 5492VL reusable patient cables are intended to be used with:
• Medtronic endocardial or myocardial pacing lead connector pins 0.38 to 2.41 mm (0.015 to 0.095 in.) in diameter and up to 25.4 mm (1.0 in.) long.
• Medtronic cardiovascular stimulating instruments.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: December 04, 2020

General Information		
Trade Name	Medtronic Model 5492A, 5492V, 5492AL, 5492VL Patient Cables	
Common Name	Patient cable	
Product Code	DSA	
Classification	II	
Regulation Number	21 CFR 870.2900	
Panel	Cardiovascular	
Predicate Device	Medtronic Model 5487/5487L Disposable Patient Cables K960446	
Submitter	Medtronic, Inc. Cardiac Rhythm Management 8200 Coral Sea Street Mounds View, MN 55112	
Contact Person	**Primary Contact** Alexandra Theisen Senior Regulatory Affairs Specialist alexandra.r.theisen@medtronic.com Tel: 763.526.6758 (direct) Fax: 651.367.0603	**Alternate Contact** Wendy Saunders Regulatory Affairs Director wendy.a.saunders@medtronic.com Tel: 763.526.8134 (direct) Fax: 651.367.0603

Brief Device Description

The 5492 A-V Patient Cables are reusable patient cables that are designed to connect a temporary pacemaker to atrial and ventricular pacing lead systems.

Indications for Use

The Medtronic Model 5492A, 5492V, 5492AL, 5492VL patient cables are intended for use as part of a temporary cardiac pacing system. They connect atrial and ventricular pacing lead systems to a temporary external pacemaker. They are intended for use by trained clinicians in a clinical environment. For more information about the intended use of and the indications for temporary cardiac pacing systems, refer to the technical manuals for the cardiovascular stimulating instruments.

The Model 5492A, 5492V, 5492AL, 5492VL reusable patient cables are intended to be used with:

- Medtronic endocardial or myocardial pacing lead connector pins 0.38 to 2.41 mm (0.015 to 0.095 in.) in diameter and up to 25.4 mm (1.0 in.) long.
- Medtronic cardiovascular stimulating instruments.

Technological Characteristics

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

When compared to the predicate device (K960446), the 5492 A-V Patient Cables presented in this submission have similar:

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

The 5492 A-V Patient Cables and the predicate device differ in the following:

- Usage (i.e. reusable versus disposable)
- Sterility (i.e. supplied non-sterile versus supplied sterile)

Substantial Equivalence and Summary of Studies:

Technological differences between the subject and predicate devices have been evaluated through bench tests. The following test data provided in this Traditional 510(k) submission has been completed:

- Sterilization (reference **Sterilization**)
- Biocompatibility (reference **Biocompatibility**)
- Electrical Safety (reference **EMC and Electrical Safety**)
- Performance Testing (reference **Performance Testing – Bench**)

Conclusion

Medtronic has demonstrated that the 5492 A-V Patient Cables described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are substantially equivalent from the predicate device.