June 7, 2024

Surgical Instrument Service and Savings Inc. (dba Medline ReNewal)
Stephanie Boyle Mays
Senior Regulatory Affairs Specialist, QA/RA
1500 NE Hemlock Ave.
Redmond, Oregon 97756

Re: K240972
Trade/Device Name: Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable (2ACHC)
Regulation Number: 21 CFR 870.1220
Regulation Name: Catheter, Recording, Electrode, Reprocessed
Regulatory Class: Class II
Product Code: NLH
Dated: April 9, 2024
Received: April 9, 2024

Dear Stephanie Boyle Mays:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Aneesh S. Deoras -S

Aneesh Deoras
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

The device(s) included in the scope of the submission are as follows:

- Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable (2ACHC)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240972

Device Name
Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable (2ACHC)

Indications for Use *(Describe)*
The cable is designed for use only with the Medtronic Achieve family of mapping catheters. It is intended to provide the connection of the catheter to a standard ECG interface box.

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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K240972 510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave., Redmond, OR 97756	
Contact/ Prepared by	Stephanie Boyle Mays Senior Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • smays@medline.com	
Date Prepared	April 9, 2024	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable
	Common or Usual Name	Catheter, recording, electrode, reprocessed
	Regulatory Name/Reference	Electrode recording catheter or electrode recording probe/21 CFR § 870.1220
	Regulatory Class	2
	Product Code	NLH
	Panel	Cardiovascular
Predicate Device	Predicate selection rationale	The predicate models in K153139 include the subject device model of this submission. The predicate catheter connecting cable device and the subject catheter connecting cable device are the same except the subject devices have been reprocessed.
	510(k) Number	K153139
	Proprietary or Trade Name	Achieve ST Mapping Catheter, Catheter Connecting Cable
	Common or Usual Name	Catheter, recording, or probe electrode recording
	Regulatory Name/Reference	Electrode recording catheter/21 CFR § 870.1220
	Regulatory Class	2
	Product Code	DRF
	Panel	Cardiovascular
	510(k) applicant	Medtronic Inc., 710 Medtronic Parkway, Minneapolis, MN 55432
Device Description	The Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable is licensed for single use only. It connects the catheter and console to provide a path of electrical transmission from the proximal end of an Achieve mapping catheter to standard shielded ECG pins that connect to standard EP pacing and recording equipment. The cable is designed to only be used with the Medtronic Achieve family of mapping catheters.	

Technological Characteristics	The technological characteristics, materials, and the fundamental scientific technology of the subject device is equivalent to the predicate device. The proposed device is a reprocessed version of the predicate device. K153139 Achieve ST Mapping Catheter, Catheter Connecting Cable was used as the primary predicate to support intended use, technological characteristics, and functional performance specifications.

Non-clinical Testing Summary	The functional characteristics of the subject device have been evaluated and found to be substantially equivalent to the predicate device based on the following tests:
	• Functional performance:
	  • simulated use and artificial soiling;
	  • visual inspection;
	  • continuity, isolation and resistance
	  • device functionality;
	• Electrical Safety
	  • current leakage and hipot
	• Cleaning Validation
	• Sterilization Validation
	  • bioburden testing;
	• Packaging and shelf life validation;
	• Product stability

Summary Table: Predicate and Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable comparison chart.

View	Predicate	Proposed	Comparison
	Medtronic Achieve ST Mapping Catheter, Catheter Connecting Cable[a]	**Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable**	**As Stated**
510(k)	K153139	K240972s	As stated
Model No.	2ACHC	2ACHC	Same
Common Name	Catheter, recording, or probe electrode recording	Catheter, recording, or probe electrode recording, reprocessed	As stated
Regulation No.	21 CFR § 870.1220	21 CFR § 870.1220	Same
Regulatory Class	2	2	Same
Product Code	DRF	NLH	Same
Indications for Use	The cable is designed for use only with the Medtronic Achieve family of mapping catheters. It is intended to provide the connection of the catheter to a standard ECG interface box.	The cable is designed for use only with the Medtronic Achieve family of mapping catheters. It is intended to provide the connection of the catheter to a standard ECG interface box.	Same

Technological Characteristics	The cable provides the connection between the Achieve catheter and the appropriate console.	The cable provides the connection between the Achieve catheter and the appropriate console.	Same
Reprocessing	Each cable is reprocessed no more than one time. Medline ReNewal does not reprocess the Achieve Catheter Connecting Cable of other reprocessors.		
Conclusion	The predicate and proposed devices in this application have the same indications for use and technological characteristics. Based on this and the non-clinical testing data presented in this 510(k) submission, the Medline ReNewal Reprocessed Medtronic Achieve Catheter Connecting Cable model 2ACHC is substantially equivalent to the predicate device.		
[a] While K153139 included both the Achieve catheter and the connecting cable, the scope of this submission includes only the cable and not the catheter or any other system components. Only device model 2ACHC is included within the scope of this project.			