November 15, 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: K241224
Trade/Device Name: Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: October 17, 2024
Received: October 17, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 following devices are included in the scope of this 510(k) premarket notification:

OEM Model No.	Description	Electrodes		Curve	Size (cm)
		Qty.	Spacing		
BD710DF282CT	7F Webster CS AID 2-8-2 DF curve with Auto ID, 115 cm	10	2-8-2	DF (64/76 mm)	7F x 115
BD710DF282RTS	7F Webster CS 2-8-2 DF curve, 115 cm	10	2-8-2	DF (64/76 mm)	7F x 115
BD710FJ282CT	7F Webster CS AID 2-8-2 FJ curve with Auto ID, 115 cm	10	2-8-2	FJ (76/102 mm)	7F x 115
BD710FJ282RTS	7F Webster CS 2-8-2 FJ curve, 115 cm	10	2-8-2	FJ (76/102 mm)	7F x 115

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)*
K241224

Device Name
Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

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) 241224 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 Inc. (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	May 1, 2024	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID
	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 1	Predicate selection rationale	The models in this submission are the same as in the predicate only that have been reprocessed
	510(k) Number	K101345
	Proprietary or Trade Name	Biosense Webster Webster CS Catheter With EZ Steer Technology, Webster CS Catheter With EZ Steer Technology and Auto ID
	Common or Usual Name	Catheter, recording, or probe electrode recording
	Regulatory Name/Reference	Electrode recording catheter or electrode recording probe/21 CFR § 870.1220
	Regulatory Class	2
	Product Code	DRF
	Panel	Cardiovascular
	510(k) applicant	Biosense Webster, 333 Diamond Canyon Rd. Diamond Bar, CA 91765
Predicate Device 2	510(k) Number	K231312
	Proprietary or Trade Name	PENTARAY NAV ECO High Density Mapping Catheter, DECANAV Mapping Catheter, Webster CS Catheter with Auto ID, Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology with Auto ID
	Common or Usual Name	Catheter, recording, or probe electrode recording

	Regulatory Name/Reference	Electrode recording catheter or electrode recording probe/21 CFR § 870.1220
Predicate 2 (concluded)	Regulatory Class	2
	Product Code	MTD, DRF
	Panel	Cardiovascular
	510(k) applicant	Biosense Webster, 333 Diamond Canyon Rd. Diamond Bar, CA 91765
Device Description/ Intended Use	Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID. The reprocessed catheters are diagnostic bi-directional 7F deflectable mapping electrophysiology EP catheters. The devices have the ability to map electrical activity within the Coronary Sinus (CS) through electrodes along the catheters' pre-shaped tip. The catheters have a braided bi-directional tip section that provides the user with two 180° opposed single plane curves (available curves are DF and FJ). The tip is deflected with a Rocker Lever, and the high torque shaft permits the tip's plane to rotate to ease accurate positioning of the catheter tip at the desired site. The Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID are equipped with an Electronically Erasable Programmable Read Only Memory (EEPROM) that is used to store unique catheter identification information.	
Indications for Use	The Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.	
Technological Characteristics	The technological characteristics, materials, and the fundamental scientific technology of the subject device is equivalent to the primary predicate devices. The proposed devices are reprocessed versions of the Webster CS predicate devices. K101345 was used as the predicate to support intended use, technological characteristics, and functional performance specifications. Each device is marked, tracked and taken out of service once the maximum number of cycles has been reached.	

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 studies:
	  • simulated use and artificial soiling;
	  • Mechanical characteristics
	  • continuity, isolation, resistance;
	  • corrosion resistance.
	• Cleaning :
	  • protein, total organic carbon
	  • visual inspection under magnification; and
	  • cleaning qualification.
	• Biocompatibility:
	  • cytotoxicity;
	  • sensitization;	

- irritation;
- acute systemic toxicity;
- materials-mediated pyrogen;
- complement activation;
- hemolysis; and
- coagulation;

- Packaging and shelf life validation
- Sterilization validation:
  - bioburden;
  - ethylene oxide/ ethylene chlorohydrin residuals;
  - bacteriostasis/fungistasis; and
  - endotoxin
- Product stability

Table 1: Comparison of Predicates and Subject devices.

PREDICATE 1	PREDICATE 2	PROPOSED	Comparison
Biosense Webster Webster CS Catheter With EZ Steer Technology, Webster CS Catheter With EZ Steer Technology and Auto ID	**Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology and Auto ID**	**Medline ReNewal Reprocessed Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID**	
510(k) number			
K101345	K231312	K241224	N/A
Model numbers			
Bi-directional catheters: BD710DF282RTS and BD710FJ282RTS *Bi-directional catheters with Auto ID:* BD710DF282CT and BD710FJ282CT[a]	*Bi-directional catheters:* D-1263-04-S & D-1263-05-S *Bi-directional catheters with Auto ID:* D-1263-06-S & D1263-07-S	*Bi-directional catheters:* BD710DF282RTS and BD710FJ282RTS *Bi-directional catheters with Auto ID:* BD710DF282CT and BD710FJ282CT	Same - Proposed and Predicate 1
Classification Name			
Catheter, electrode recording, or electrode recording probe	Catheter, Intracardiac Mapping, High-Density Array	Catheter, recording, electrode recording, reprocessed	Same - Proposed and Predicate 1
Regulation No.			
21 CFR § 870.1220	21 CFR § 870.1220	21 CFR § 870.1220	Same
Regulatory Class			
2	2	2	Same
Product Code			

PREDICATE 1	PREDICATE 2	PROPOSED	Comparison
Biosense Webster Webster CS Catheter With EZ Steer Technology, Webster CS Catheter With EZ Steer Technology and Auto ID	**Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology and Auto ID**	**Medline ReNewal Reprocessed Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID**	
DRF	MTD, DRF	NLH	As stated
Technological Characteristics			
The Webster CS Catheters have a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing and have bi-directional deflection and a usable length of 115 cm. Auto ID models are equipped with an Electronically Erasable Programmable Read Only Memory (EEPROM) that is used to store unique catheter identification information.. Catheters interface with a Carto EP Navigation Systems via an interface cable with the appropriate connectors.	The Webster CS is identical in design and all technological characteristics to the Webster CS catheter cleared in K101345. The main difference between the predicate device and the modified device is a change to the instructions for use to allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation.	The Webster CS Catheters have a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing and have bi-directional deflection and a usable length of 115 cm. Auto ID models are equipped with an Electronically Erasable Programmable Read Only Memory (EEPROM) that is used to store unique catheter identification information.. Catheters interface with a Carto EP Navigation Systems via an interface cable with the appropriate connectors.	Same
Indications for Use			
Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.	Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.	Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.	Same
Reprocessing			

PREDICATE 1	PREDICATE 2	PROPOSED	Comparison
Biosense Webster Webster CS Catheter With EZ Steer Technology, Webster CS Catheter With EZ Steer Technology and Auto ID	**Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology and Auto ID**	**Medline ReNewal Reprocessed Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID**	
Each cable is reprocessed no more than two times. Medline ReNewal does not reprocess the Webster CS Catheters 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 Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID are substantially equivalent to the predicate device.			

[a] Original equipment manufacturer models were associated with the K101345 predicate by consulting the GUDID database.