June 5, 2025

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: K250545
Trade/Device Name: Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR eco Diagnostic Ultrasound Catheters (8F, 8FG, 10F, 10FG)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ, OBJ
Dated: February 24, 2025
Received: February 25, 2025

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	Shaft size
Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter 8F		
10439236	8FG ultrasound catheter for use on GE systems, 64-element phased array and 3D location sensor, four-way tip deflection	8F x 90 cm
10439011	8F Ultrasound catheter for use on Siemens systems, 64-element phased array and 3D location sensor, four-way tip deflection	8F x 90 cm
Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter 10F		
10439072	10FG ultrasound catheter for use on GE systems, 64-element phased array and 3D location sensor, four-way tip deflection	10F x 90 cm
10438577	10F ultrasound catheter for use on Siemens systems, 64-element phased array and 3D location sensor, four-way tip deflection	10F x 90 cm

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)*
K250545

Device Name
Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR eco Diagnostic Ultrasound Catheters (8F, 8FG, 10F, 10FG)

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR eco Diagnostic Ultrasound Catheters 8F, 8FG, 10F 10FG are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO 3 EP Navigation Systems, the SOUNDSTAR eco Catheter provides location information.

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

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 Specialist, Regulatory Affairs Quality Assurance P: 541-516-4205 • F: 541-923-3375 • smays@medline.com	
Date Prepared	February 24, 2025	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters (8F, 8FG, 10F, 10FG)
	Common or Usual Name	Ultrasound catheter, reprocessed
	Regulatory Name/Reference	Reprocessed intravascular, ultrasound catheter, 21 CFR § 870.1200
	Regulatory Class	2
	Product Code	OWQ
	Panel	Cardiovascular
Predicate Device 1	Predicate selection rationale	The predicate models in K140318 include the 8FG and 8F subject device models of this submission. The predicate devices and subject devices are the same except the subject devices have been reprocessed.
	510(k) Number	K140318
	Proprietary or Trade Name	SOUNDSTAR eco 8FG Ultrasound Catheter, SOUNDSTAR eco 8F Ultrasound Catheter
	Common or Usual Name	Ultrasound catheter
	Regulatory Name/Reference	Catheter, ultrasound, intravascular 21 CFR § 870.1200
	Regulatory Class	2
	Product Code	OBJ
	Panel	Cardiovascular
	510(k) applicant	Biosense Webster 3333 Diamond Canyon Rd., Baldwin Bar, CA 91765
Predicate Device 2	Predicate selection rationale	The predicate models in K112050 include the 10FG and 10F subject device models of this submission. The predicate devices and subject devices are the same except the subject devices have been reprocessed.
	510(k) Number	K112050
	Proprietary or Trade Name	Soundstar eco Diagnostic Ultrasound Catheter

	Common or Usual Name	Ultrasound catheter
Predicate Device 2 (concluded)	Regulatory Name/Reference	Catheter, ultrasound, intravascular 21 CFR § 870.1200
	Regulatory Class	2
	Product Code	OBJ
	Panel	Cardiovascular
	510(k) applicant	Biosense Webster 3333 Diamond Canyon Rd., Baldwin Bar, CA 91765
Device Description	The Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters 8F, 8FG, 10F, 10FG are licensed for single use only. Models differ in shaft diameter (8F or 10F) and ultrasound system compatibility (Siemens [8F and 10F] or GE [8FG and 10FG]). The catheter consists of a CARTO connector, SwiftLink (ultrasound) connector, handle and shaft. In the distal tip of each catheter's shaft are a 64-element ultrasound transducer providing 2D imaging and a 3D location sensor providing location information to the compatible CARTO 3 Electrophysiology (EP) Navigation System. The deflection and tension knobs on the handle are used to articulate the distal tip and control the image plane orientation with four-directional (anterior-posterior, left-right) deflection.	
Technological Characteristics	The technological characteristics, materials, and the fundamental scientific technology of the subject devices are equivalent to the predicate devices. The subject devices are reprocessed versions of the predicate device. Each device is marked, tracked, and taken out of service once the maximum number of cycles has been reached. K140318 and K112050 were used as the predicates to support intended use, technological characteristics, and functional performance specifications.	

Non-clinical Testing Summary	Functional characteristics of the subject devices have been evaluated and found to be substantially equivalent to the predicate devices based on:
	• Functional performance:
	  • simulated use and artificial soiling;
	  • visual inspection;
	  • mechanical characteristics;
	  • ultrasound transducer testing;
	  • dimensional analysis
	  • localization; and
	  • device functionality
	• Electrical Safety:
	  • dielectric and current leakage
	• Cleaning Validation
	• Biocompatibility
	• Sterilization Validation
	  • bioburden testing;
	  • ethylene oxide and ethylene chlorohydrin residuals testing;
	  • bacteriostasis/fungistasis
	• Packaging and shelf life validation
	• Product stability	

Summary Table: **Predicates and Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter comparison chart.**

Device Characteristics	Predicate 1	Predicate 2	Proposed	Comparison
	Biosense Webster SOUNDSTAR eco 8FG Ultrasound Catheter, SOUNDSTAR eco 8F Ultrasound Catheter	**Biosense Webster SOUNDSTAR eco Diagnostic Ultrasound Catheter**	**Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters 8F, 8FG, 10F, 10FG**	**As Stated**
510(k)	K140318	K112050	TBD	N/A
Model/Numbers	8F (10439011); 8FG (10439236)	10F (10438577); 10FG (10439011	8F (10439011); 8FG (10439236) 10F (10438577); 10FG (10439011)	Same
Common Name	Ultrasound catheter	Ultrasound catheter	Ultrasound catheter Reprocessed	As stated
Regulation No.	21 CFR § 870.1200	21 CFR § 870.1200	21 CFR § 870.1200	Same
Regulatory Class	2	2	2	Same
Product Code	OBJ	OBJ	OWQ	As stated
Indications for Use	The Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO 3 EP Navigation Systems, the SOUNDSTAR *eco* Catheter provides location information.	The Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO 3 EP Navigation Systems, the SOUNDSTAR *eco* Catheter provides location information.	The Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters 8F, 8FG, 10F 10FG are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO 3 EP Navigation Systems, the SOUNDSTAR *eco* Catheter provides location information.	Same

(continued)

Summary Table: **Predicates and Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheter comparison chart (concluded).**

Device Characteristics	Predicate 1 **Biosense Webster SOUNDSTAR eco 8FG Ultrasound Catheter, SOUNDSTAR eco 8F Ultrasound Catheter**	Predicate 2 **Biosense Webster SOUNDSTAR eco Diagnostic Ultrasound Catheter**	Proposed **Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters 8F, 8FG, 10F, 10FG**	Comparison **As Stated**
Technological Characteristics[a]	To operate, the device is connected to a compatible console via a SwiftLink connector (8F is compatible with Siemens systems; 8FG is compatible with GE systems).	To operate, the device is connected to a compatible console via a SwiftLink connector (10F is compatible with Siemens systems; 10 FG is compatible with GE systems).	To operate, the device is connected to a compatible console via a SwiftLink connector (8F and 10F are compatible with Siemens; 8FG and 10FG are compatible with GE systems).	Same
Reprocessing	Each catheter is reprocessed no more than one time. Medline ReNewal does not reprocess the catheters of other reprocessors.			
Conclusion	The predicate and subject 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 SOUNDSTAR *eco* Diagnostic Catheters 8F, 8FG, 10F, 10FG are substantially equivalent to the predicate devices.			

[a] The current submission does not include consoles or any other system components as part of this respective submissions. Only Medline ReNewal Reprocessed Biosense Webster SOUNDSTAR *eco* Diagnostic Ultrasound Catheters 8F, 8FG, 10F, 10FG are included in the project scope.