September 10, 2024

Surgical Instrument Service and Savings Inc. (dba Medline Renewal)
Stephanie Boyle Mays
Senior Specialist, Regulatory Affairs Quality Assurance
1500 NE Hemlock Ave.
Redmond, Oregon 97756

Re: K234064
Trade/Device Name: Medline ReNewal Reprocessed Siemens ACUSON AcuNav 8F Ultrasound Catheter (for Siemens Systems) (10135936); Medline ReNewal Reprocessed Siemens ACUSON AcuNav 8F Ultrasound Catheter (for GE Systems) (10135910)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: August 12, 2024
Received: August 12, 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 item numbers included in the scope of this submission are as follows:

OEM Model No.	Transducer	Curve	Size
10135910	GE Systems - 64 element phased array	Four-way tip deflection: anterior/posterior; left/right	8 F x 90 cm
10135936	Siemens Systems - 64 element phased array	Four-way tip deflection: anterior/posterior; left/right	8 F x 90 cm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234064

Device Name
Medline ReNewal Reprocessed Siemens ACUSON AcuNav Diagnostic Ultrasound Catheter, 8F (for Siemens Systems) (10135936);
Medline ReNewal Reprocessed Siemens ACUSON AcuNav Diagnostic Ultrasound Catheter, 8F (for GE Systems) (10135910)

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Siemens ACUSON AcuNav Diagnostic Ultrasound Catheter is intended 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 of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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) 234064 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	December 21, 2023	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Siemens ACUSON AcuNav 8F Ultrasound Catheter (for Siemens Systems) (10135936); Medline ReNewal Reprocessed Siemens ACUSON AcuNav 8F Ultrasound Catheter (for GE Systems) (10135910)
	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	Predicate selection rationale	The predicate models in K170263 include the 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	K170263
	Proprietary or Trade Name	AcuNav Diagnostic Ultrasound Catheter 8F, 10F
	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	Siemens Medical Solutions, 685 E. Middlefield Rd., Mountain View, CA 94043
Device Description	The Medline ReNewal Reprocessed AcuNav Diagnostic Ultrasound Catheters 8F are licensed for single use only. The catheter is optimized for intracardiac scanning. With the catheter, the physician can maneuver the imaging plane located inside the catheter tip to see the region of interest. The physician can steer the catheter to optimize tissue visualization.	

	The catheters are to be used only on systems with which they have been tested and found compatible.
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. Each device is marked, tracked, and taken out of service once the maximum number of cycles has been reached. K170263 AcuNav Diagnostic Ultrasound Catheter 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;
	  • mechanical characteristics
	  • ultrasound transducer testing
	  • dimensional analysis
	  • device functionality;
	• Electrical Safety
	  • dielectric and current leakage
	• Cleaning Validation
	• Biocompatibility
	• Sterilization Validation
	  • bioburden testing; and
	  • ethylene oxide and ethylene chlorohydrin residuals testing
	  • bacteriostasis/fungistasis
	• Packaging and shelf life validation
	• Product stability

Summary Table: Predicate and Medline ReNewal Reprocessed AcuNav Diagnostic Ultrasound Catheter comparison chart.

View	**Predicate**	**Proposed**	**Comparison**
	Siemens Medical Solutions AcuNav Diagnostic Ultrasound Catheter	**Medline ReNewal Reprocessed Siemens ACUSON AcuNav Diagnostic Ultrasound Catheter 8F**	**As Stated**
510(k)	K170263	234064	N/A
Model Numbers	10135936 and 10135910, 8F 08255790 and 10043372, 10F	10135936 and 10135910 8F	As stated
Common Name	Ultrasound catheter	Ultrasound catheter Reprocessed	As stated
Regulation No.	21 CFR § 870.1200	21 CFR § 870.1200	Same
Regulatory Class	2	2	Same

Product Code	OBJ	OWQ	As stated
Indications for Use	The catheter is intended 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 of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The Medline ReNewal Reprocessed Siemens ACUSON AcuNav Diagnostic Ultrasound Catheter 8F is intended 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 of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	Same
Technological Characteristics [a]	To operate, the device is connected to a compatible console (ACUSON, Vivid I, Vivid q) via a compatible module interface.	To operate, the device is connected to a compatible console (ACUSON, Vivid I, Vivid q) via a compatible module interface.	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 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 AcuNav Ultrasound Catheter 8F models 10135936 and 10135910 are substantially equivalent to the predicate device.		

[a] Neither K170263 nor the current submission included the consoles or any other system components as part of their respective submissions. Only devices 10135936 and 10135910 are included in the project scope.