December 15, 2023

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

Re: K232130
Trade/Device Name: Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: November 15, 2023
Received: November 15, 2023

Dear Stephanie 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	Tip Deflection	Size
ViewFlex Xtra ICE Catheter			
D087031	64 element phased array	120 degree	9 Fr 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)*
K232130

Device Name
Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.

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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K232130 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	July 17, 2023	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter
	Common or Usual Name	ICE Catheter, Reprocessed
	Regulatory Name/Reference	Diagnostic intravascular catheter, reprocessed 21 CFR § 870.1200
	Regulatory Class	2
	Product Code	OWQ
	Panel	Cardiovascular
Predicate Device	510(k) Number	K133853
	Proprietary or Trade Name	ViewFlex Xtra ICE Catheter
	Common or Usual Name	ICE Catheter
	Regulatory Name/Reference	Diagnostic intravascular catheter, 21 CFR § 870.1200
	Regulatory Class	2
	Product Code	OBJ
	Panel	Cardiovascular
	Manufacturer	Irvine Biomedical, Inc. a St. Jude Medical Company 2374 Morse Ave., Irvine, CA 92614
Model intended for reprocessing	ViewFlex Xtra ICE Catheter D087031	Transducer: 64 element phased array Tip deflection: 120 degree Size: 9 Fr x 90 cm
Device Description	The Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The reprocessed ViewFlex Xtra is a sterile, single use, temporary, intracardiac catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is	

	deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles. Each device is marked and tracked and taken out of service once the maximum number of cycles has been reached.
Intended Use	The Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.
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. K133853 ViewFlex Xtra ICE 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
	• Electrical Safety
	  • Dielectric and current leakages
	• Cleaning Validation:
	• Biocompatibility:
	• Sterilization Validation
	• Packaging and shelf life validation; sterilization validation:
	  • bioburden testing; and
	  • ethylene oxide and ethylene chlorohydrin residuals testing
	  • bacteriostasis/fungistatis
	• Product stability

Summary Table: Predicate and Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter comparison chart.

View	**Predicate**	**Proposed**	**Comparison**
	ViewFlex Xtra Ice Catheter	**Medline ReNewal Reprocessed ViewFlex Xtra Ice Catheter**	**As Stated**
510(k)	K133853	K232130	N/A
Model Number	Not listed in K133853 Summary	D087031	As stated
Common Name	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter, Reprocessed	As stated

Summary table concluded

View	Predicate	Proposed	Comparison
	ViewFlex Xtra Ice Catheter	**Medline ReNewal Reprocessed ViewFlex Xtra Ice Catheter**	**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 (Intended Use)	ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.	The Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.	Same
Technological Characteristics[a]	To operate, the catheter is connected to a compatible intracardiac ultrasound console (View Mate II, ViewMate Z and Philips CX50) via a compatible ViewFlex Catheter Interface Module.	To operate, the catheter is connected to a compatible intracardiac ultrasound console (View Mate II, ViewMate Z and Philips CX50) via a compatible ViewFlex Catheter Interface Module.	Same
Reprocessing	Each catheter is reprocessed no more than two times. 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 ViewFlex Xtra ICE Catheter device model listed in this summary table is substantially equivalent to the predicate device.		

[a] Neither K133853 nor the current submission included the interface module or generators as part of their respective submissions. Only the catheter model is included in the project scope.