May 31, 2023

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

Re: K221067
Trade/Device Name: Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: NLH
Dated: May 4, 2023
Received: May 4, 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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 model numbers included in the scope of this submission are listed in the following table.

Model No.	Description	Electrodes		Curve	Size (cm)[a]
		Qty.	Spacing		
401572	Quadripolar	4	2-5-2	M Sweep	6 Fr x 115
401575	Decapolar	10	2-5-2	M Sweep	6 Fr x 115
401580	Hexapolar	6	2-5-2	M Sweep	7 Fr x 115
401581	Octapolar	8	2-5-2	M Sweep	7 Fr x 115
401582	Decapolar	10	2-5-2	M Sweep	7 Fr x 115
401600	Quadripolar	4	2-5-2	M Sweep	6 Fr x 115
401603	Quadripolar	4	2-5-2	M Curl	6 Fr x 115
401606	Quadripolar	4	2-5-2	L Sweep	6 Fr x 115
401648	Quadripolar	4	5-5-5	L Curl	5 Fr x 115
401652	Octapolar	8	2-2-2	M Sweep CRD-2™	5 Fr x 115
401653	Hexapolar	6	2-5-2	M Sweep CRD-2™	5 Fr x 115
401654	Hexapolar	6	5	M Sweep CRD-2™	5 Fr x 115
401655	Decapolar	10	5-5-5	XL Curl	5 Fr x 115
401780	Quadripolar	4	5-5-5	M sweep	5 Fr x 115
401904	Duo-Decapolar	20	2-10-2	Super L Curl	7 Fr x 95
401905	Duo-Decapolar	20	5-5-5	Super L Curl	7 Fr x 95
401908	Duo-Decapolar	20	2-2-2	M Curl	7 Fr x 115
401914	Duo-Decapolar	20	2-5-2	Super L Curl	7 Fr x 95
401915	Decapolar	10	2-5-2	XL Curl	6 Fr x 115
401917	Octapolar	8	2-2-2	M Sweep	6 Fr x 115
401918	Duo-Decapolar BDB™	20	2-20-2-2-2-2-2-2-2-2-2-2-25-2-25-2-25-2	Super L Curl	7 Fr x 95
401923	Decapolar	10	2-2-2	XL Curl	6 Fr x 115
401926	Decapolar CSL™ Bi-directional	10	2-8-2	XL Sweep CSL	6 Fr x 115
401932	Dual-Purpose Duo-Decapolar (20 Electrodes)	20	2-8-2-(60)-2-8-2	Super L Curl	7 Fr x 95
401933	Quadripolar	4	5-5-5	M Sweep	6 Fr x 115
401934	Quadripolar	4	5-5-5	L Sweep	6 Fr x 115
401935	Decapolar	10	2	XL Sweep	7 Fr x 115
401938	Decapolar	10	5-5-5	M Sweep	5 Fr x 115

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)*
K221067

Device Name
Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheters

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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.

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221067 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 8, 2022	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheters
	Common or Usual Name	Diagnostic Electrophysiology Catheter, 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	510(k) Number	K151622
	Proprietary or Trade Name	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter, Livewire Electrophysiology Catheter, Response Electrophysiology Catheter with Lumen, Response Electrophysiology Catheter and SJM Epicardial Catheter System, Supreme Electrophysiology Catheter
	Common or Usual Name	Diagnostic Electrophysiology Catheter
	Regulatory Name/Reference	Electrode recording catheter or electrode recording probe, 21 CFR § 870.1220
	Regulatory Class	2
	Product Code	DRF
	Panel	Cardiovascular
	Manufacturer	St. Jude Medical 14901 DeVeau Place, Minnetonka, MN 55345
Device Description	The Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter is a flexible electrode catheter constructed of a polyurethane insulation/shaft and incorporates platinum electrodes. The active tip may be manipulated by a remote means located at the proximal end of the catheter.	
Indications for use	The Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	

Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are equivalent to the predicate device. The proposed devices are a reprocessed version of the predicate devices. K151622 St. Jude Medical Livewire Steerable Electrophysiology 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 studies:
	  • simulated use and artificial soiling;
	  • tensile testing;
	  • torsional strength;
	  • leakage current;
	  • continuity;
	  • isolation
	  • resistance;
	  • three-point bend
	  • corrosion resistance.
	• Cleaning:
	  • protein, total organic carbon, and endotoxins;
	  • visual inspection under magnification; and
	  • cleaning performance qualification.
	• Biocompatibility:
	  • cytotoxicity;
	  • sensitization;
	  • irritation;
	  • acute systemic toxicity;
	  • materials-mediated pyrogen
	  • complement activation;
	  • hemolysis (direct and indirect)
	  • coagulation
	  • complement activation
	  • thrombosis.
	• 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 St. Jude Medical Livewire Reprocessed Electrophysiology Catheter device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter, Livewire Electrophysiology	**Medline ReNewal St. Jude Medical Livewire Steerable Electrophysiology Catheter**	**As Stated**

	Catheter, Response Electrophysiology Catheter with Lumen, Response Electrophysiology Catheter and SJM Epicardial Catheter System, Supreme Electrophysiology Catheter		
510(k)	K151622	TBD	N/A
Model Numbers	Not listed in K151622 Summary	401572, 401575, 401580, 401581, 401582, 401600, 401603, 401606, 401648, 401652, 401653, 401654 401655, 401780, 401904, 401905, 401908, 401914, 401915, 401917, 401918, 401923, 401926, 401932, 401933, 401934, 401935, 401938, 401939, 401940, 401941, 401949, 401990, 401991, 402022, 402032	As stated
Common Name	Diagnostic Electrophysiology Catheter	Diagnostic Electrophysiology Catheter, Reprocessed	As stated
Regulation No.	21 CFR § 870.1220	21 CFR § 870.1220	Same
Regulatory Class	2	2	Same
Product Code	DRF	NLH	As stated
Indications for Use (Intended Use)	The Livewire Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	The Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	Same

Summary Table: Predicate and Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable EP Catheters device comparison chart (concluded).

Device Characteristics	Predicate	Proposed	Comparison
	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter, Livewire Electrophysiology Catheter, Response Electrophysiology Catheter with Lumen, Response Electrophysiology Catheter and SJM Epicardial Catheter System, Supreme Electrophysiology Catheter	**Medline ReNewal St. Jude Medical Livewire Steerable Electrophysiology Catheter**	**As stated**
Technological Characteristics[a]	To operate, the Livewire Steerable Electrophysiology Catheters are connected to a generator via a universal cable.	To operate, the Medline ReNewal Reprocessed Livewire Steerable Electrophysiology Catheters are connected to a generator via a universal cable.	As stated
[a] Neither K151622 nor the current submission included the universal cable or generators as part of their respective submissions. Only catheter models were included in the project scope.			
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 St. Jude Medical Livewire Steerable Catheter device models listed in this summary table are substantially equivalent to the predicate devices.		