September 14, 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: K241156
Trade/Device Name: Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheter, Supreme 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: August 19, 2024
Received: August 19, 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 item numbers included in the scope of this submission are as follows:

| OEM Part No. | Description | Electrodes (Qty.) | Electrode Spacing (mm) | Curve | Size (diameter/length) |
|---|---|---|---|---|---|
| **Response Catheter Models** | | | | | |
| 401150 | Decapolar | 10 | 2-10-2 | CRD™ | 6 Fr, 120 cm |
| 401206 | Quadripolar | 4 | 10 | CRD™ | 5 Fr, 120 cm |
| 401207 | Quadripolar | 4 | 10 | JSN™ | 5 Fr, 120 cm |
| 401210 | Quadripolar | 4 | 10 | CRD™ | 6 Fr, 120 cm |
| 401211 | Quadripolar | 4 | 10 | JSN™ | 6 Fr, 120 cm |
| 401212 | Quadripolar | 4 | 10 | DAO™ | 6 Fr, 120 cm |
| 401222 | Quadripolar | 4 | 5 | CRD™ | 5 Fr, 120 cm |
| 401223 | Quadripolar | 4 | 5 | JSN™ | 5 Fr, 120 cm |
| 401226 | Quadripolar | 4 | 5 | CRD™ | 6 Fr, 120 cm |
| 401227 | Quadripolar | 4 | 5 | JSN™ | 6 Fr, 120 cm |
| 401228 | Quadripolar | 4 | 5 | DAO™ | 6 Fr, 120 cm |
| 401260 | Quadripolar | 4 | 2-5-2 | CRD™ | 6 Fr, 120 cm |
| 401261 | Quadripolar | 4 | 2-5-2 | JSN™ | 6 Fr, 120 cm |
| 401271 | Hexapolar | 6 | 2-5-2 | JSN™ | 6 Fr, 120 cm |
| 401305 | Decapolar | 10 | 2-5-2 | CRD™ | 6 Fr, 120 cm |
| 401306 | Decapolar | 10 | 2-5-2 | JSN™ | 6 Fr, 120 cm |
| 401309 | Decapolar | 10 | 2-5-2 | JSN™ | 6 Fr, 65 cm |
| 401310 | Decapolar | 10 | 2-5-2 | DAO™ | 6 Fr, 65 cm |
| 401311 | Decapolar | 10 | 2-2-2 | CRD™ | 6 Fr, 120 cm |
| 401312 | Decapolar | 10 | 2-2-2 | JSN™ | 6 Fr, 120 cm |
| 401317 | Bipolar | 2 | 10 | CRD™ | 6 Fr, 120 cm |
| 401353 | Decapolar | 10 | 2-8-2 | CSL™ | 6 Fr, 65 cm |
| 401357 | Quadripolar | 4 | 5 | JSN-1™ | 6 Fr, 120 cm |
| 401381 | Decapolar | 10 | 2-8-2 | CSL™ | 6 Fr, 120 cm |
| 401392 | Decapolar | 10 | 2-2-2 | CSL™ | 6 Fr, 120 cm |
| 401399 | Decapolar | 10 | 5-5-5 | CSL™ | 6 Fr, 120 cm |
| 401400 | Decapolar | 10 | 5-5-5 | CSL™ | 6 Fr, 65 cm |
| 401425 | Hexapolar | 6 | 5-5-5-150-5 | CRD™ | 6 Fr, 120 cm |

| OEM Part No. | Description | Electrodes (Qty.) | Electrode Spacing (mm) | Curve | Size (diameter, length) |
|---|---|---|---|---|---|
| **Supreme Catheter Models** | | | | | |
| 401430 | Quadripolar | 4 | 5 | JSN™ | 6 Fr, 120 cm |
| 401433 | Quadripolar | 4 | 10 | CRD™ | 5 Fr, 120 cm |
| 401434 | Quadripolar | 4 | 10 | CRD™ | 6 Fr, 120 cm |
| 401435 | Quadripolar | 4 | 10 | JSN™ | 5 Fr, 120 cm |
| 401436 | Quadripolar | 4 | 10 | JSN™ | 6 Fr, 120 cm |
| 401438 | Quadripolar | 4 | 10 | DAO™ | 6 Fr, 120 cm |
| 401441 | Quadripolar | 4 | 5 | CRD™ | 5 Fr, 120 cm |
| 401442 | Quadripolar | 4 | 5 | CRD™ | 6 Fr, 120 cm |
| 401443 | Quadripolar | 4 | 5 | JSN™ | 5 Fr, 120 cm |
| 401444 | Quadripolar | 4 | 5 | DAO™ | 5 Fr, 120 cm |
| 401445 | Quadripolar | 4 | 5 | DAO™ | 6 Fr, 120 cm |
| 401448 | Quadripolar | 4 | 2-5-2 | CRD™ | 5 Fr, 120 cm |
| 401449 | Quadripolar | 4 | 2-5-2 | CRD™ | 6 Fr, 120 cm |
| 401450 | Quadripolar | 4 | 2-5-2 | JSN™ | 5 Fr, 120 cm |
| 401451 | Quadripolar | 4 | 2-5-2 | JSN™ | 6 Fr, 120 cm |
| 401453 | Quadripolar | 4 | 2-5-2 | DAO™ | 6 Fr, 120 cm |
| 401466 | Quadripolar | 4 | 5 | DAO-1™ | 5 Fr, 120 cm |
| 401468 | Quadripolar | 4 | 2-5-2 | DAO-1™ | 5 Fr, 120 cm |
| 401474 | Quadripolar | 4 | 5 | CRD-1™ | 6 Fr, 120 cm |
| 401475 | Quadripolar | 4 | 5 | JSN-1™ | 6 Fr, 120 cm |
| 401859 | Quadripolar | 4 | 10 | CRD-2™ | 5 Fr, 120 cm |
| 401860 | Quadripolar | 4 | 5 | CRD-2™ | 5 Fr, 120 cm |
| 401863 | Decapolar | 10 | 2-8-2 | CSL™ | 5 Fr, 120 cm |
| 401864 | Decapolar | 10 | 2-8-2 | CSL™ | 5 Fr, 65 cm |
| 401865 | Decapolar | 10 | 5-5-5 | CSL™ | 5 Fr, 120 cm |
| 401876 | Hexapolar | 6 | 5-5-5-175-175 | CRD-1™ | 6 Fr, 120 cm |
| 401877 | Hexapolar | 6 | 5-5-5-175-175 | JSN™ | 6 Fr, 120 cm |
| 401878 | Hexapolar | 6 | 5-5-5-175-175 | JSN™ | 5 Fr, 120 cm |
| 401890 | Quadripolar | 4 | 5-5-5 | JSN™ | 4 Fr, 120 cm |
| 401891 | Quadripolar | 4 | 5-5-5 | CRD™ | 4 Fr, 120 cm |
| 401892 | Quadripolar | 4 | 5-5-5 | DAO™ | 4 Fr, 120 cm |
| 401893 | Decapolar | 10 | 2-8-2 | CSL™ | 4 Fr, 65 cm |

| OEM Part No. | Description | Electrodes (Qty.) | Electrode Spacing (mm) | Curve | Size (diameter, length) |
|---|---|---|---|---|---|
| Supreme Catheter Models (concluded) | | | | | |
| 401966 | Hexapolar | 6 | 5-5-5 | CRD-2™ | 4 Fr, 120 cm |
| 401967 | Hexapolar | 6 | 2-2-2 | CRD-2™ | 4 Fr, 120 cm |
| 401979 | Decapolar | 10 | 2-5-2 | CSL™ | 4 Fr, 65 cm |
| 401994 | Quadripolar | 4 | 2-5-2 | JSN™ | 4 Fr, 120 cm |
| 401996 | Quadripolar | 4 | 2-5-2 | CRD™ | 4 Fr, 120 cm |
| 402004 | Quadripolar | 4 | 5 | CRD-2™ | 6 Fr, 120 cm |
| 402008 | Hexapolar | 6 | 2-5-2 | CRD-2™ | 5 Fr, 120 cm |
| 402009 | Hexapolar | 6 | 5-5-5 | CRD-2™ | 5 Fr, 120 cm |
| 402010 | Hexapolar | 6 | 2-5-2 | CRD-2™ | 6 Fr, 120 cm |
| 402011 | Hexapolar | 6 | 5-5-5 | CRD-2™ | 6 Fr, 120 cm |
| 402012 | Quadripolar | 4 | 5-5-5 | CRD-2™ | 4 Fr, 120 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)*
K241156

Device Name
Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheter, Supreme Electrophysiology Catheter

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheters and Supreme Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmia 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) 241156

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)<br>1500 NE Hemlock Ave., Redmond, OR 97756 | |
| **Contact/ Prepared by** | Stephanie Boyle Mays<br>Senior Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs<br>P: 541-516-4205 • F: 541-923-3375 • smays@medline.com | |
| **Date Prepared** | April 25, 2024 | |
| **Device Name and Classification** | Proprietary/Trade Name: | Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheter, Supreme Electrophysiology Catheter |
| | 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** | Predicate selection rationale | The predicate models in K151622 include the subject device models of this submission. |
| | 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 | 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 | St. Jude Medical,<br>14901 DeVeau Place, Minnetonka, MN 55345 |
| **Reference Device** | Reference device rationale | Reference and proposed devices share original equipment manufacturer, predicate device, similar materials, indications for use, intended use, and processes. |
| | 510(k) Number | K221067 |

| | | |
|---|---|---|
| Reference device concluded | Proprietary or Trade Name | Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter |
| | 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 | NLH |
| | Panel | Cardiovascular |
| | 510(k) applicant | Surgical Instrument Service and Savings (dba Medline ReNewal)<br>1500 NE Hemlock Ave., Redmond, OR 97756 |
| **Device Description/ Intended Use** | Medline ReNewal Reprocessed St. Jude Medical Supreme and Response Electrophysiology Catheters are commonly placed at the high right atrium, right ventricular apex and His bundle, and in the coronary sinus, and are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The Medline ReNewal Reprocessed St. Jude Medical Supreme and Response Electrophysiology Catheters are fixed electrode catheters constructed of a polyurethane insulation/shaft and incorporate platinum electrodes.<br>Each device is marked and tracked and will be taken out" of service once the maximum number of cycles has been reached. | |
| **Indications for Use** | The Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheters and Supreme Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmia from endocardial and intravascular sites. | |
| **Technological Characteristics** | The technological characteristics, materials, and the fundamental scientific technology of the subject device is equivalent to the predicate and reference devices. The proposed devices are reprocessed versions of the Supreme and Response predicate devices. K151622 was used as the primary predicate to support intended use, technological characteristics, and functional performance specifications. K221067 was used as a reference device to further demonstrate substantial equivalency. | |
| **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:<br>• Functional performance studies:<br>  • simulated use and artificial soiling;<br>  • Mechanical characteristics<br>  • continuity, isolation, resistance;<br>  • Corrosion resistance.<br>• Cleaning :<br>  • protein, total organic carbon<br>  • visual inspection under magnification; and<br>  • Cleaning qualification.<br>• Biocompatibility:<br>  • cytotoxicity; | |

- sensitization;
- irritation;
- acute systemic toxicity;
- materials-mediated pyrogen;
- complement activation;
- thrombosis; and
- hemocompatibility

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

**Summary Table: Predicate, Reference and Proposed Device Comparison Chart**

| **PREDICATE 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** | **REFERENCE**<br><br>**Medline ReNewal Reprocessed St. Jude Medical Livewire Steerable Electrophysiology Catheter** | **PROPOSED**<br><br>**Medline ReNewal Reprocessed St. Jude Medical Supreme and Response Electrophysiology Catheters** | **Comparison** |
|---|---|---|---|
| **510(k) number** | | | |
| K151622 | K221067 | K241156 | N/A |
| **Model number** | | | |
| 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 | 401150, 401206, 401207, 401210, 401211, 401212, 401222, 401223, 401226, 401227, 401228, 401260, 401261, 401271, 401305, 401306, 401309, 401310, 401311, 401312, 401317, 401353, 401357, 401381, 401392, 401399, 401400, 401425, 401430, 401433, 401434, 401435, 401436, 401438, 401441, 401442, 401445, 401443, 401444, | Same |

| | | | |
|---|---|---|---|
| | | 401448, 401449, 401450, 401451, 401453, 401466, 401468, 401474, 401475, 401859, 401860, 401863, 401864, 401865, 401876, 401877, 401878, 401890, 401891, 401892, 401893, 401966, 401967, 401979, 401994, 401996, 402004, 402008, 402009, 402010, 402011, 402012 | |
| **Classification Name** | | | |
| Catheter, electrode recording, or probe electrode recording | Catheter, recording, electrode recording, reprocessed | Catheter, recording, electrode recording, reprocessed | As stated |
| **Regulation No.** | | | |
| 21 CFR § 870.1220 | 21 CFR § 870.1220 | 21 CFR § 870.1220 | Same |
| **Regulatory Class** | | | |
| 2 | 2 | 2 | Same |
| **Product Code** | | | |
| DRF | NLH | NLH | As stated |
| **Indications for Use** | | | |
| St. Jude Medical Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites. | Medline ReNewal Reprocessed Livewire Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites. | Medline ReNewal Reprocessed St. Jude Medical Response Electrophysiology Catheters and Supreme Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmia from endocardial and intravascular sites. | Same |
| **Technological Characteristics** | | | |
| The SJM Electrophysiology Supreme and Response Catheters contain various fixed curves and electrode spacings. | The Medline ReNewal Reprocessed St. Jude Medical Livewire Electrophysiology Catheters contain various electrode spacings and a steerable design with a tip that can be shaped into a user-desired curve | The Medline ReNewal Reprocessed St. Jude Medical Supreme and Response Electrophysiology Catheters contain various fixed curves and electrode spacings. | As stated |
| **Reprocessing** | | | |
| Each subject catheter is reprocessed no more than one time. Medline ReNewal does not reprocess the Supreme and Response Electrophysiology Catheters of other reprocessors. | | | |
| **Conclusion** | | | |

The predicate, reference 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 Supreme and Response Electrophysiology Catheters within the scope of this submission are substantially equivalent to the predicate device.