November 29, 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: K242225
Trade/Device Name: Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: November 1, 2024
Received: November 1, 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 following devices are included in the scope of this 510(k) premarket notification:

| OEM Model No. | Diameter (Fr) | Length (cm) | Electrodes | | Curve |
|---|---|---|---|---|---|
| | | | Qty. | Spacing (mm) | |
| 81102 | 6 | 110 | 10 | 2-5-2 | M |
| 81104 | 6 | 110 | 10 | 2-5-2 | L |
| 81105 | 6 | 110 | 10 | 2-5-2 | XL |
| 81107 | 6 | 110 | 10 | 5 | L |
| 81171 | 5 | 110 | 10 | 2 | M |
| 81172 | 5 | 110 | 10 | 2-5-2 | M |
| 81174 | 5 | 110 | 10 | 2-5-2 | L |
| 81202 | 7 | 110 | 20 | 2-10-2 | XXL |
| 81207 | 7 | 110 | 20 | 5 | SL |
| 81209 | 7 | 110 | 20 | 2-5-2 | SL |
| 81223 | 5 | 110 | 10 | 2(50)3 | XL |
| 81224 | 5 | 110 | 10 | 2(30)3 | M |
| 81402 | 6 | 110 | 4 | 2-5-2 | M |
| 81403 | 6 | 110 | 4 | 5 | M |
| 81404 | 6 | 110 | 4 | 2-5-2 | L |
| 81405 | 6 | 110 | 4 | 5 | L |
| 81417 | 6 | 110 | 4 | 5 | XL |
| 81418 | 6 | 110 | 4 | 2-5-2 | XL |
| 81472 | 5 | 110 | 4 | 2-5-2 | M |
| 81473 | 5 | 110 | 4 | 5 | M |
| 81474 | 5 | 110 | 4 | 2-5-2 | L |
| 81483 | 5 | 110 | 4 | 5 | E(HIS) |
| 81504 | 6 | 110 | 10 | 5 | M |
| 81520 | 6 | 110 | 10 | 2 | XL |
| 81521 | 5 | 110 | 5 | 5(170) | M/L |
| 81524 | 6 | 110 | 10 | 2 | L |
| 81526 | 5 | 95 | 10 | 2-170-170 | C1(HIS) |
| 81530 | 4 | 110 | 10 | 2 | M |
| 81531 | 4 | 110 | 10 | 2-5-2 | M |
| 81532 | 4 | 110 | 10 | 2-5-2 | L |
| 81534 | 4 | 110 | 10 | 5 | L |
| 81537 | 4 | 60 | 10 | 2-5-2 | M(SC) |
| 81540 | 4 | 110 | 4 | 2-5-2 | M |
| 81542 | 4 | 110 | 4 | 5 | M |
| 81543 | 4 | 110 | 4 | 2-5-2 | L |
| 81557 | 5 | 110 | 10 | 3(170)50 | M |
| 81721 | 5 | 110 | 10 | 2-5-2 | M(SC) |
| 81730 | 5 | 110 | 10 | 2-8-2 | M/L |
| 81734 | 5 | 110 | 10 | 2-5-2 | L |
| 81735 | 5 | 110 | 10 | 5 | L |
| 81736 | 5 | 110 | 10 | 5(22)5 | M/L |
| 81801 | 6 | 110 | 8 | 2 | M |
| 81802 | 6 | 110 | 8 | 2-5-2 | M |
| 81807 | 6 | 110 | 8 | 2 | L |
| 81809 | 6 | 110 | 8 | 2-5-2 | L |
| 81871 | 5 | 110 | 8 | 2 | M |
| 81872 | 5 | 110 | 8 | 2-5-2 | M |
| 81945 | 6 | 110 | 10 | 2-5-2 | L |
| 81947 | 6 | 110 | 10 | 5 | M/L |

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.*

Submission Number *(if known)*

K242225

Device Name

Medline ReNewal Reprocessed  Abbott Inquiry Steerable Diagnostic Catheter

Indications for Use *(Describe)*

Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheters can be used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the HIS bundle.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) 242225 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)<br>1500 NE Hemlock Ave., Redmond, OR 97756 | |
| **Contact/ Prepared by** | Stephanie Boyle Mays<br>Senior Regulatory Affairs Specialist, Regulatory Affairs<br>P: 541-516-4205 • F: 541-923-3375 • smays@medline.com | |
| **Date Prepared** | July 26, 2024 | |
| **Device Name and Classification** | Proprietary/Trade Name: | Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic 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 |
| **Predicates selection** | Rationale | The predicate models in K982232 and K961924 include the subject device models of this submission. |
| **Predicate Device (1)** | 510(k) Number | K982232 |
| | Proprietary or Trade Name | Modification of the IBI-1100 Steerable Electrophysiology Catheter System |
| | 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 | Irvine BioMedical, Inc.,<br>2146-A Michelson Dr., Irvine, CA 92612 |
| **Predicate Device (2)** | 510(k) Number | K961924 |
| | Proprietary or Trade Name | IBI-1100 Steerable Electrophysiology Catheter System |
| | 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 | Irvine BioMedical, Inc.,<br>2146-A Michelson Dr., Irvine, CA 92612 |
| **Device Description/ Intended Use** | The Medline ReNewal Reprocessed Inquiry Steerable Diagnostic Electrophysiology Catheters are flexible, insulated catheters constructed of thermoplastic elastomer material and noble metal electrodes. The tip of the steerable catheters may be manipulated with the control mechanism located in the handle of the proximal end of the catheter. | |
| **Indications for Use** | Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic catheters can be used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the HIS bundle. | |
| **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 predicate devices. Each device undergoes a validated process that includes cleaning, inspections and functional tests, packaging and sterilization. Devices are tracked to ensure they do not exceed the number of validated reprocessing cycles (2). Devices that have reached the maximum number of cycles or do not meet inspection criteria are rejected and disposed of appropriately. The predicate devices were used 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:<br>• Functional performance studies:<br>  • visual inspection;<br>  • dimensional measurement;<br>  • electrical safety;<br>  • mechancial characteristics<br>  • continuity, isolation, resistance; and<br>  • corrosion resistance.<br>• Cleaning validation<br>• Biocompatibility<br>• Packaging and shelf life validation<br>• Sterilization validation<br>• Product stability | |

**Summary Table follows**

**Summary Table: Predicates and Proposed Device Comparison Chart**

| PREDICATE 1 Modification of the IB-1100 Steerable Electrophysiology Catheter System | PREDICATE 2 IBI-1100 Steerable Electrophysiology Catheter System | PROPOSED Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter | Comparison |
|---|---|---|---|
| **510(k) number** | | | |
| K982232 | K961924 | TBD | N/A |
| **Model number** | | | |
| Not listed in K982232 Summary | Not listed in K961924 Summary | 81102, 81104, 81105, 81107, 81171, 81172, 81174, 81202, 81207, 81209, 81223, 81224, 81402, 81403, 81404, 81405, 81417, 81418, 81472, 81473, 81474, 81483, 81504, 81520, 81521, 81524, 81526, 81530, 81531, 81532, 81534, 81537, 81540, 81542, 81543, 81557, 81721, 81730, 81734, 81735, 81736, 81801, 81802, 81807, 81809, 81871, 81872, 81945, 81947 | As stated |
| **Classification Name** | | | |
| Catheter, electrode recording, or probe electrode recording | Catheter, electrode recording, or probe electrode recording | 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 | DRF | NLH | As stated |
| **Indications for Use** | | | |
| Electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the HIS bundle | Electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the HIS bundle | Electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the HIS bundle | Same |

| Technological Characteristics | | | |
|---|---|---|---|
| The catheters contain various numbers of electrodes and electrode spacings and a steerable design with a tip that are available in various curves. | The catheters contain various numbers of electrodes and electrode spacings and a steerable design with a tip that are available in various curves. | The Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheters contain various numbers of electrodes and electrode spacings and a steerable design with a tip that are available in various curves. | Same |
| **Reprocessing** | | | |
| Each catheter is reprocessed no more than two times. Medline ReNewal does not reprocess the Inquiry Steerable Diagnostic Catheters of other reprocessors. | | | |
| **Conclusion** | | | |
| The predicates 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 Abbott Inquiry Steerable Diagnostic Catheters within the scope of this submission are substantially equivalent to the predicate devices. | | | |