December 19, 2025

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

Re: K250314
Trade/Device Name: Medline ReNewal Reprocessed Abbott Agilis Nxt Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: May 29, 2025
Received: May 30, 2025

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,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2025.12.19 12:57:36 -05'00'

For
Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: 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:

Device Model Number	Device Name//Description	Introducer F Size (inner)	Introducer/Dilator Total Lengths (cm)	Introducer Curl Type	OEM[a]
408309	Abbott Agilis NxT Steerable Introducer	8.5	91/94	Small	Abbott
408310	Abbott Agilis NxT Steerable Introducer	8.5	91/94	Medium	Abbott
G408318[b]	Abbott Agilis NxT Steerable Introducer	8.5	81/84	Small	Abbott
G408319	Abbott Agilis NxT Steerable Introducer	8.5	81/84	Medium	Abbott
G408320	Abbott Agilis NxT Steerable Introducer	8.5	91/94	Small	Abbott
G408321	Abbott Agilis NxT Steerable Introducer	8.5	91/94	Medium	Abbott
G408324	Abbott Agilis NxT Steerable Introducer	8.5	91/94	Large	Abbott

[a] OEM = original equipment manufacturer
[b] All models prefixed with a "G" have "improved kink resistance."

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)*
K250314

Device Name
Medline ReNewal Reprocessed Abbott Agilis NxT Steerable Introducer

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Abbott Agilis NxT Steerable Introducer is indicated for the introduction of various cardiovascular catheters into the heart, including the left side of the heart, during the treatment of cardiac arrhythmias.

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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510(k) K250314 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 Specialist, Regulatory Affairs Quality Assurance P: 541-516-4205 • F: 541-923-3375 • smays@medline.com	
Date Prepared	December 19, 2025	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Abbott Agilis NxT Steerable Introducer
	Common or Usual Name	Introducer, Catheter Reprocessed
	Regulatory Name/Reference	Catheter Introducer/21 CFR § 870.1340
	Regulatory Class	2
	Product Code	PNE
	Panel	Cardiovascular
Predicate Device	Predicate selection rationale	The predicate models in K251211 include subject device models of this submission.
	510(k) Number	K251211 (Type = Special)
	Proprietary or Trade Name	Agilis NxT Steerable Introducer
	Common or Usual Name	Introducer, Catheter
	Regulatory Name/Reference	Catheter Introducer 21 CFR § 870.1340
	Regulatory Class	2
	Product Code	DYB
	Panel	Cardiovascular
	510(k) applicant	Abbott Medical., 5050 Nathan Lane, Plymouth, Minnetonka, MN 55345-2126
Device Description	The Medline ReNewal Reprocessed Agilis NxT Steerable Introducer consists of a dilator, guidewire, and a bi-directional steerable introducer, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The device has either a small, medium, or large curl at the distal tip. The sheath handle is equipped with a rotating collar to deflect the tip clockwise ≥ 180° and counterclockwise ≥ 90°. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization. The sheath material consists of braided stainless-steel wire covered with Pebax (polyether block amide) and Nylon. The sheath is filled with barium sulfate, and the distal tip has a	

	platinum/iridium marker for visualization under fluoroscopy. A plastic dilator and stainless-steel guidewire are packaged with the introducer and are designed to facilitate the introduction and passage of the introducer through the vasculature.
Indications for Use	The Medline ReNewal Reprocessed Abbott Agilis NxT Steerable Introducer is indicated for the introduction of various cardiovascular catheters into the heart, including the left side of the heart, during the treatment of cardia arrhythmias.
Device Models in Scope	408309, 408310, G408318, G408319, G408320, G408321, G408324
Technological Characteristics	The technological characteristics, materials, and the fundamental scientific technology of the subject device is equivalent to the predicate and reference devices. The subject devices are reprocessed versions of the predicate device. 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 (1 cycle maximum). Devices that have reached the maximum number of cycles or do not meet inspection criteria are rejected and disposed of appropriately. The predicate device was used to support intended use, technological characteristics, and functional performance specifications.

Non-clinical Testing Summary	Functional characteristics of the subject devices have been evaluated and found to be substantially equivalent to the predicate devices based on:
	• Functional performance:
	  • simulated use and artificial soiling;
	  • visual inspection
	  • insertion force, torque response, kink, occlusion, leak, tensile strength and performance, deflection durability, friction, barcode scannability, and particulate testing studies
	  • mechanical characteristics;
	  • visual and dimensional analysis
	• Cleaning validation
	• Biocompatibility validation
	• Sterilization validation
	  • bioburden;
	  • bacterial endotoxin;
	  • ethylene oxide and ethylene chlorohydrin residuals;
	  • bacteriostasis/fungistasis
	• Packaging and shelf-life validation

Reprocessing	Each Abbott Agilis NxT introducer is reprocessed no more than one time. Medline ReNewal does not reprocess the Abbott Agilis NxT Introducer of other reprocessors.
Conclusion	The predicate and subject 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 Agilis NxT Steerable Introducer models within the scope of this submission are substantially equivalent to the predicate devices.