January 7, 2026

Innovative Health
Meerna Muradvich
Regulatory Affairs Engineer
1435 N. Hayden Rd.
Suite 100
Scottsdale, Arizona 85257

Re: K250305
Trade/Device Name: Reprocessed Agilis NxT Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: October 3, 2025
Received: October 6, 2025

Dear Meerna Muradvich:

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: 2026.01.07 09:57:57 -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:

Description	Item Number	French Size		Useable Length (cm)	Curve Type	Curve Reach (mm)
		ID	OD			
Reprocessed Agilis NxT Steerable Introducer	408309	8.5F	11.5F	71	Small Curl Dual Reach Bi-Directional	16.8
	408310	8.5F	11.5F	71	Medium Curl Dual Reach Bi-Directional	22.4
	G408324	8.5F	11.5F	71	Large Curl Dual Reach Bi-Directional	50.0
	G408318	8.5F	11.5F	61	Small Curl Dual Reach Bi-Directional	16.8
	G408319	8.5F	11.5F	61	Medium Curl Dual Reach Bi-Directional	22.4
	G408320	8.5F	11.5F	71	Small Curl Dual Reach Bi-Directional	16.8
	G408321	8.5F	11.5F	71	Medium Curl Dual Reach Bi-Directional	22.4

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)*
K250305

Device Name
Reprocessed Agilis NxT Steerable Introducer

Indications for Use *(Describe)*
The Reprocessed 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) Summary

Submitter's Name and Address:
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Contact Name and Information:
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Date prepared:
January 31, 2025

Device Information:

Trade/Proprietary Name:	Reprocessed Agilis NxT Steerable Introducer
Common Name:	Steerable Introducer
Classification Name:	Reprocessed Catheter Introducer
Classification Number:	Class II, 21 CFR 870.1340
Product Code:	PNE

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K251211	Agilis NxT Steerable Introducer	St. Jude Medical/Abbott

Reference Device:

510(k) Number	510(k) Device	Manufacturer
K170311	Reprocessed Agilis NxT Steerable Introducer	Innovative Health, LLC.
K230376	Reprocessed Agilis NxT Steerable Introducer	Innovative Health, LLC.

Device Description:
The Reprocessed Agilis NxT Steerable Introducer consists of a dilator, guidewire, and 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 a 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.

Note: Only the steerable sheath and dilator are the subject (reprocessed devices) of this submission. The guidewire is purchased off-the shelf (K935170) and packaged with the reprocessed devices.

Indications for Use:
The Reprocessed 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.

The item numbers included in the scope of this submission are as follows:

Description	Item Number	French Size		Useable Length (cm)	Curve Type	Curve Reach (mm)
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	G408319	8.5F	11.5F	61	Medium Curl Dual Reach Bi-Directional	22.4
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	G408321	8.5F	11.5F	71	Medium Curl Dual Reach Bi-Directional	22.4

Table 1: Item Numbers

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Agilis NxT Steerable Introducer is identical to the predicate device. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of this device includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

Functional and Safety Testing:
Bench and laboratory testing evaluated substantial equivalence of the Reprocessed Agilis NxT Steerable Introducer to the predicate device.

This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
    - Visual Inspection
    - Dimensional Verification
    - Tensile Testing
    - Deflection Testing
    - Simulated Use Testing
    - Leak Testing
    - Radiopacity Testing
    - Particulate Testing
    - Friction Testing
- Packaging Validation

The Reprocessed Agilis NxT Steerable Introducer is reprocessed no more than two (2) times. Each device is marked, serialized, and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing. Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Innovative Health concludes that the testing evaluated substantial equivalence to the predicate devices described herein.