December 13, 2024

Abbott Medical
Juan Ordonez
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, Minnesota 55345

Re: K243493
Trade/Device Name: Agilis NxT Steerable Introducer Dual-Reach
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 8, 2024
Received: November 12, 2024

Dear Juan Ordonez:

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: 2024.12.13 14:22:20 -05'00'

Finn Donaldson
Acting 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

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)*
K243493

Device Name
Agilis NxT Steerable Introducer Dual-Reach

Indications for Use *(Describe)*
The Agilis NxT Steerable Introducer Dual-Reach 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.

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510(k) Information	
510(k) Number	K243493
510(k) Type	Special 510(k)
Date Prepared	12-Dec-2024
Submitter Information	
Manufacturer Name & Address	Abbott Medical 14901 DeVeau Place Minnetonka, MN 55345 USA
Contact Person	Juan Ordonez Sr. Regulatory Affairs Specialist 612-619-8354 juan.ordonez3@abbott.com
Device Information	
Trade Name	Agilis™ NxT Steerable Introducer Dual-Reach™
Common Name	Introducer, Catheter
Class	II
Classification Name	21 CFR 870.1340 Catheter Introducer
Product Code	DYB - Introducer, catheter
Predicate Device	Agilis™ NxT Steerable Introducer Dual-Reach (K241370 – Cleared on 13thJune-2024)
Device Description	The Agilis™ NxT Steerable Introducer Dual-Reach™ is a sterile, single-use device that consists of a dilator and steerable introducer, which is designed to provide flexible catheter positioning in the cardiac anatomy. The inner diameter of the steerable introducer is 13F. The steerable introducer includes a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. It has a sideport with a three-way stopcock for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The 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.
Indications for Use	The Agilis™ NxT Steerable Introducer Dual-Reach™ 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.
Predicate Comparison	
Comparison of technological Characteristics	The subject device, Agilis™ NxT Steerable Introducer Dual-Reach™, and the predicate device, Agilis™ NxT Steerable Introducer Dual-Reach (K241370) have the same intended use and indications for use. They use the same fundamental scientific technology to facilitate catheter introduction into the heart. The subject device was modified to include: • Additional curl (medium and large) deflectable configurations • A distal tip wall thickness reduction • An increase in pull ring, pull wires and braid wire size • An improved pull wire lock mechanism • A minor modification to the side port location of the hemostasis hub • A packaging tray adoption from 8.5F Agilis models • A minor modification to the deflection angle All risks associated with these modifications were mitigated to acceptable levels. No new questions of safety or effectiveness were raised.

Predicate Comparison Continued	
Non-Clinical Testing Summary	Design verification activities were performed and met the respective acceptance criteria to ensure that the devices in scope of this submission are safe and effective. **Testing** The Agilis™ NxT Steerable Introducer Dual-Reach™ was developed and tested in accordance with the following industry guidance documents and standards: • Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations, issued October 10, 2019 • ISO 80369-7 Section Edition 2021-05, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications • ANSI AAMI ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ANSI AAMI ISO 11135:2014/A1:2018, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release • ANSI AAMI ST72:2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing • ISO 11607-1 Second edition 2019-02 [Including AMD1:2023], Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)] • ISO 11607-2 Second edition 2019-02, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes • ISO 15223-1 Fourth edition 2021-07, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements • ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices - Information to be supplied by the manufacturer **Types of Testing Performed** • Performance testing of modified design • Biocompatibility testing • Sterility testing • Shelf-life
Statement of Equivalence	The subject and predicate devices have the same intended use, and the same indications for use. The devices operate using the same fundamental scientific technology to facilitate catheter introduction into the heart. The testing completed and summarized in this Special 510(k) provides objective evidence that the subject device is substantially equivalent to the predicate device.