May 23, 2025

Abbott Medical
Adam Bakken
Senior Specialist, Regulatory Affairs
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K251211
Trade/Device Name: ViewFlex™ Xtra ICE Catheter; ViewFlex™ Eco Reprocessed ICE Catheter; Advisor™ HD Grid Mapping Catheter, Sensor Enabled™; Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™; Agilis™ NxT Steerable Introducer; Agilis™ NxT Steerable Introducer Dual-Reach™
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, OWQ, MTD, DYB
Dated: April 17, 2025
Received: April 18, 2025

Dear Adam Bakken:

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

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)*

K251211

Device Name

ViewFlex™ Xtra ICE Catheter;
ViewFlex™ Eco Reprocessed ICE Catheter;
Advisor™ HD Grid Mapping Catheter, Sensor Enabled™;
Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™;
Agilis™ NxT Steerable Introducer;
Agilis™ NxT Steerable Introducer Dual-Reach™

Indications for Use *(Describe)*

ViewFlex™ Xtra ICE Catheter
The ViewFlex™ Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac, structures, blood flow and other devices within the heart.

ViewFlex™ Eco Reprocessed ICE Catheter
The ViewFlex™ Eco Reprocessed Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

Advisor™ HD Grid Mapping Catheter, Sensor Enabled™
The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™
The Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

Agilis™ NxT Steerable Introducer
The 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.

Agilis™ NxT Steerable Introducer Dual-Reach™
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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ATTACHMENT 12 – 510(K) SUMMARY

510(k) Information	
510(k) Number	K251211
510(k) Type	Bundled Special 510(k)
Date Prepared	04-17-2025
Submitter Information	
Manufacturer Name and Address	Abbott Medical 5050 Nathan Lane North Plymouth, MN 55442 USA
Phone Number	701-388-0504
Contact Person	Adam Bakken Senior Specialist, Regulatory Affairs
Device Information (ViewFlex)	
Trade Name	ViewFlex™ Xtra ICE Catheter
Common Name	ICE Catheter
Class	II
Classification Name	21 CFR 870.1200, Diagnostic Intravascular Catheter
Product Code	OBJ
Predicate Device	ViewFlex™ Xtra ICE Catheter (K223077)
Device Description	The ViewFlex™ Xtra ICE catheter is a temporary intracardiac ultrasound catheter intended for use in patients to accurately visualize cardiac structures, blood flow and other devices within the heart when connected to a compatible intracardiac ultrasound console via the compatible ViewFlex™ Catheter Interface Module. Examples of the types of other devices that can be visualized include, and are not limited to, intracardiac catheters, septal occluders, delivery wires, delivery sheaths, sizing balloons and transseptal needles. The use of these images is limited to visualization with no direct or indirect diagnostic use. The ViewFlex™ Xtra ICE catheter has a useable length of 90 cm, with a 9 French (F) shaft with an ultrasound transducer. A 10F introducer is recommended for use with this catheter for insertion into the femoral or jugular veins. The catheter tip has four-directional deflection allowing for Left-Right and Posterior-Anterior deflection, with an angle of at least 120 degrees in each direction.
Indications for Use	The ViewFlex™ Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac, structures, blood flow and other devices within the heart

510(k) Information	
Device Information (ViewFlex)	
Trade Name	ViewFlex™ Eco Reprocessed ICE Catheter
Common Name	Reprocessed ICE Catheter
Class	II
Classification Name	21 CFR 870.1200, Diagnostic Intravascular Catheter
Product Code	OWQ
Predicate Device	ViewFlex™ Eco Reprocessed ICE Catheter (K231588)
Device Description	The ViewFlex™ Eco Reprocessed ICE Catheter is a temporary intracardiac ultrasound catheter intended for use in patients to accurately visualize cardiac structures, blood flow and other devices within the heart when connected to a compatible intracardiac ultrasound console via the compatible ViewFlex™ Catheter Interface Module. Examples of the types of other devices that can be visualized include, and are not limited to, intracardiac catheters, septal occluders, delivery wires, delivery sheaths, sizing balloons and transseptal needles. The use of these images is limited to visualization with no direct or indirect diagnostic use. The ViewFlex™ Reprocessed Catheter has a useable length of 90 cm, with a 9 French (F) shaft with an ultrasound transducer. A 10F introducer is recommended for use with this catheter for insertion into the femoral or jugular veins. The catheter tip has four-directional deflection allowing for Left-Right and Posterior-Anterior deflection, with an angle of at least 120 degrees in each direction.
Indications for Use	The ViewFlex™ Eco Reprocessed Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.
Device Information (Advisor HD Grid)	
Trade Name	Advisor™ HD Grid Mapping Catheter, Sensor Enabled™
Common Name	Catheter, Intracardiac Mapping, High-Density Array
Class	II
Classification Name	21 CFR 870.1220 Electrode recording catheter or electrode recording probe
Product Code	MTD
Predicate Device	Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K202066)

510(k) Information	
Device Description	The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is a sterile, single-use, irrigated, high-density mapping catheter with a 7.5F shaft and an 8F distal shaft deflectable section. It is available in a D-F bi-directional curve model that is deflected using the actuator located on the catheter handle. The catheter working length is 110 cm. The device consists of a paddle-shaped distal tip with 16 electrodes, two distal shaft ring electrodes, two magnetic sensors, polymer braided shaft, handle, fluid lumen extension with a luer, and an electrical connector. The Advisor HD Grid catheter also has an introducer tool intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an introducer sheath.
Indications for Use	The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.
Device Information (Advisor HD Grid X)	
Trade Name	Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™
Common Name	Catheter, Intracardiac Mapping, High-Density Array
Class	II
Classification Name	21 CFR 870.1220 Electrode recording catheter or electrode recording probe
Product Code	MTD
Predicate Device	Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ (K241372)
Device Description	The Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ (Grid X), is a sterile, single-use, irrigated high-density mapping catheter that is a diagnostic catheter for performing electrophysiology-mapping procedures and provides pacing signals to the heart. A single Grid X model is offered with a 7.5F shaft and an 8F distal shaft deflectable section. It is available in a D-F bi-directional curve model that is deflected using the actuator located on the catheter handle. The catheter working length is 110 cm. The device consists of a paddle-shaped distal tip with 16 electrodes, with two reference electrodes placed proximal to the paddle on the distal end of the catheter shaft. The catheter also includes a 6DOF (degree of freedom) sensor capability for the shaft through the use of two magnetic sensors located at the distal end of the shaft, as well as independent 5DOF sensor capability for the paddle through an additional two magnetic sensors located in the distal end of the outer paddle splines. The electrode spacing is such that multiple bi-pole pairs can be created to support acquisition of additional mapping points. The catheter design includes irrigation at the proximal end of the paddle. The Grid X catheter also has an insertion tool intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an introducer sheath.

510(k) Information	
Indications for Use	The Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.
Device Information (Agilis™ NxT Steerable Introducer)	
Trade Name	Agilis™ NxT Steerable Introducer
Common Name	Introducer, Catheter
Class	II
Classification Name	21 CFR 870.1340 Introducer, Catheter
Product Code	DYB
Predicate Device	Agilis™ NxT Steerable Introducer (K061363)
Device Description	The 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 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.
Device Information (Agilis™ NxT Steerable Introducer Dual-Reach)	
Trade Name	Agilis™ NxT Steerable Introducer Dual-Reach™
Common Name	Introducer, Catheter
Class	II
Classification Name	21 CFR 870.1340 Introducer, Catheter
Product Code	DYB
Predicate Device	Agilis™ NxT Steerable Introducer Dual-Reach™ (K243493)

510(k) Information	
Device Description	The Agilis™ NxT Steerable Introducer Dual-Reach™ is a sterile, single-use device that con-sists 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 intro-duction and/or exchange. It has a sideport with 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	All technological characteristics are the same – no proposed changes between the subject and predicate devices.
Non-Clinical Testing Summary	Bench-testing was not necessary to validate the Clinical Workflow modifications. Substantial Equivalence of the subject devices to the predicate devices using the zero/low fluoroscopy workflow has been supported through a summary of clinical data across multiple studies in which investigators used alternative visualization methods.
Statement of Equivalence	The Agilis NxT™ Steerable Introducer Indications for Use statement was modified to clarify the conditions of use. The modifications to the Agilis™ NxT Steerable Introducer indications for use statement do not introduce a new intended use or raise different questions of safety or effectiveness. The subject devices have the same intended use and technological characteristics as their respective predicate devices. Based on data provided in this pre-market notification, the subject devices are as safe and effective as their respective predicate devices and, therefore, are substantially equivalent to them.