May 20, 2025

Abbott Medical
Kyle Nevala
Senior Regulatory Affairs Specialist
2375 Morse Avenue
Irvine, California 92614

Re: K251231
Trade/Device Name: ViewFlex™ X ICE Catheter, Sensor Enabled™
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: April 21, 2025
Received: April 22, 2025

Dear Kyle Nevala:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251231

Please provide the device trade name(s).

ViewFlex™ X ICE Catheter, Sensor Enabled™

Please provide your Indications for Use below.

The ViewFlex™ X ICE Catheter Sensor Enabled™ is indicated for use in adult and adolescent pediatric patients for intra-cardiac and intra-luminal visualization of cardiac and great vessels anatomy and physiology, as well as visualization of other devices in the heart. When used with a compatible three-dimensional mapping system, the catheter provides location information.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

This 510(k) summary is prepared in accordance with the requirements of 21 CFR §807.92.

510(k) Information	
510(k) Number	K251231
510(k) Type	Special 510(k)
Date Prepared	April 21, 2025
Submitter Information	
Manufacturer Name and Address	Abbott Medical 2375 Morse Avenue Irvine, CA 92614 USA
Phone Number	651-756-3828
Contact Person	Kyle Nevala Senior Regulatory Affairs Specialist
Device Information	
Trade Name	ViewFlex™ X ICE Catheter, Sensor Enabled™
Common Name	Catheter, Ultrasound, Intravascular
Class	2
Classification Name	21 CFR 870.1200 – Diagnostic intravascular catheter
Product Code	OBJ – Catheter, Ultrasound, Intravascular
Predicate Device	ViewFlex™ Xtra ICE Catheter (K223077, cleared 07-Dec-2022)
Reference Device	N/A
Device Description	The ViewFlex™ X ICE Catheter Sensor Enabled™ (SE) is a sterile, single use, temporary, radiopaque, intracardiac ultrasound catheter. The catheter shaft is a 9 French (F) catheter constructed with flexible tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer. The distal portion of the shaft is deflectable utilizing two handle mechanisms which create four deflection directions including left, right, anterior and posterior. The distal tip contains an ultrasound transducer and 3-D location sensor providing 2-D imaging and 3-D location and orientation information when used with a compatible ultrasound system and the EnSite X Cardiac Mapping System.
Indications for Use	The ViewFlex™ X ICE Catheter Sensor Enabled™ is indicated for use in adult and adolescent pediatric patients for intra-cardiac and intra-luminal visualization of cardiac and great vessels anatomy and physiology, as well as visualization of other devices in the heart. When used with a compatible three-dimensional mapping system, the catheter provides location information.

510(k) Information	
Predicate Comparison	
Comparison of Technological Characteristics	The subject device has an equivalent indications for use and the same intended use and principles of operation as the predicate device, and has substantially equivalent technological characteristics to the predicate device. Like the predicate, the subject device is an intra-cardiac echocardiography (ICE) catheter. Additional catheter components were modified from the predicate to accommodate the addition of magnetic sensors within the flexible tip, improve manufacturability, and improve material stability for continuous improvement purposes. The predicate and subject device have the same working length, shaft French size, and same connection to the ViewFlex™ Catheter Interface Module.
Non-Clinical Testing Summary	Bench design verification activities were performed and met their respective acceptance criteria to ensure that the device in scope of this submission is substantially equivalent to the predicate. Testing included dimensional, visual, mechanical integrity, simulated use, electrical, packaging, and shelf-life testing to assess substantial equivalence. Additionally, biocompatibility testing was conducted per the voluntary consensus standards under ISO 10993 and met all the biocompatibility endpoints for a medical device category for an external communicating medical device with limited (≤24 hour) circulating blood contact.
Statement of Equivalence	The subject device has equivalent indications for use and intended use and the same principles of operation and fundamental use, and equivalent technological characteristics to the predicate device. Completed bench design verification testing, biocompatibility testing, and pre-clinical evaluation provides objective evidence that the subject device is at least as safe and effective as the predicate and is therefore substantially equivalent to the predicate.