December 7, 2022

Irvine Biomedical, a St. Jude Medical Company
Suzanne Pekarna
Senior Specialist Regulatory Affairs
2375 Morse Ave
Irvine, California 92614

Re: K223077
Trade/Device Name: ViewFlex™ Xtra ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: September 29, 2022
Received: September 30, 2022

Dear Suzanne Pekarna:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223077

Device Name
ViewFlex™ Xtra ICE Catheter

Indications for Use *(Describe)*
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.

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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Special 510(k) K223077
ViewFlex™ Xtra ICE Catheter
Compatibility with ViewMate™ Multi Ultrasound System

510(k) Information	
510(k) Number	K223077
510(k) Type	Special 510(k)
Date Prepared	29 September 2022
Submitter Information	
Manufacturer Name & Address	Irvine Biomedical, a St. Jude Medical Company[1] 2375 Morse Ave Irvine, CA 92614, USA
Contact Person	Suzanne Pekarna Senior Specialist Regulatory Affairs 651-756-4601 suzanne.pekarna@abbott.com
Device Information:	
Trade Name	ViewFlex™ Xtra ICE Catheter
Common Name	ICE Catheter
Class	II
Classification Name	870.1200, Diagnostic Intravascular Catheter
Product Code	OBJ
Subsequent Product Code	OBJ
Predicate Device	ViewFlex™ Xtra ICE Catheter (K133853)
Reference Device	Not Applicable
Device Description	The ViewFlex™ Xtra ICE Catheter ("ViewFlex™ 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™ 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. The ViewFlex™ Catheter is compatible with the ViewMate™ Z, ViewMate™, ViewMate™ Multi, and Philips CX50 ultrasound consoles.
Indication 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.
Patient Population	The patient population includes both adult and adolescent pediatric patients with suspected or confirmed cardiac electrical or structural abnormalities who require visualization of cardiac structures, blood flow, or other devices within the heart. The testing performed supports safety and effectiveness in both (adult and adolescent pediatric) patient populations.
Predicate Comparison	
Comparison	Both the subject and predicate devices have the same intended use, indications for use and method of operation. There are no changes to the

[1] Abbott Medical is a registered trade name for the Irvine Biomedical, Inc., a St Jude Medical Company.

510(k) Information	
	claims, clinical applications, patient populations, or performance specifications. The current compatible consoles for the predicate deice are the ViewMate Z (K101091), ViewMate (K192410), and Philips CX50 (K123754) Ultrasound consoles. The subject device is compatible with these consoles as well as the ViewMate™ Multi Ultrasound System (K222754, currently under review). The predicate device IFU does not list ViewMate™ Multi Ultrasound System as a compatible console. Each device is inspected and functionally tested prior to packaging, labeling and sterilizing. The differences between the subject ViewFlex™ Catheter and the predicate device does not raise any new questions of safety and effectiveness.
Non-Clinical Testing Summary	Design verification activities were performed with their respective acceptance criteria to ensure that the use of the ViewFlex™ Xtra ICE Catheter in conjunction with the ViewMate™ Multi Ultrasound System does not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. **Testing** The ViewFlex™ XTRA ICE Catheter was tested in accordance with the following industry guidance documents and standards: – BS EN 60601-2-37: 2008+A1:2015 - Medical electrical equipment: Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.BS EN 60601-1: 2006+A12:2014 (Edition 3.1) - Medical electrical equipment: General requirements for basic safety and essential performance. – BS EN 60601-1-2:2015 (Edition 4.0) - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests. **Types of Testing Performed** – Design validation – Design verification **Risk Management** There were no new or modified hazards identified as a result of the proposed modifications. Abbott has reviewed the applicable risk management documentation for the addition of the ViewMate™ Multi Ultrasound System and determined that the changes described in Section 3.1 of the Special 510(k) submission do not increase existing risks or create new risks to the user or patient, and that the residual risk remains acceptable following verification and validation activities. Updates to the risk analysis were limited to addition of the ViewMate™ Multi Ultrasound System and the addition of test reports related to the modifications.
Statement of Equivalence	The technological characteristics for the subject device, and the indications for use are the same as the predicate device. Based on this and the verification and validation data provided in this pre-market notification, the subject device and predicate device have been demonstrated to be substantially equivalent.