December 19, 2022

Abbott Medical
Quynh Phuong Le
Regulatory Affairs Project Manager
14901 Deveau Place
Minnetonka, Minnesota 55345

Re: K222217
Trade/Device Name: ViewFlex™ Xtra Reprocessed ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ, OBJ
Dated: December 13, 2022
Received: December 14, 2022

Dear Quynh Phuong Le:

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

The following device is included in the scope of this 510(k) submission:

Description	Reference Model Number (Predicate)	Reprocessed Model Number (Subject)	Usable Length	French Size	System Compatibility
ViewFlex™ Xtra Reprocessed ICE Catheter	D087031	D087031-R	90cm	9F	ViewMate™ Z ViewMate™ Philips CX 50

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)*
K222217

Device Name
ViewFlex™ Xtra Reprocessed ICE Catheter

Indications for Use *(Describe)*
The ViewFlex™ Xtra Reprocessed 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.

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510(k) Summary

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

510(k) Type	Traditional 510(k)
Date Prepared	22 July 2022
Manufacturer Name & Address	Abbott Medical 14901 DeVeau Place Minnetonka, MN 55345-2126, USA
Contact Person	Quynh Phuong Le Regulatory Affairs Project Manager 949-769-5058 or 949-469-9779 quynphuong.le@abbott.com
Trade Name	ViewFlex™ Xtra Reprocessed ICE Catheter
Common Name	ICE Catheter
Class	II
Classification Name	870.1200, Diagnostic Intravascular Catheter
Product Code	OWQ
Subsequent Product Code	OBJ
Predicate Device	ViewFlex™ Xtra ICE Catheter (K133853)
Device Description	The ViewFlex™ Xtra 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™ Xtra Reprocessed 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. The ViewFlex™ Xtra Reprocessed ICE Catheter is compatible with the ViewMate™ Z, ViewMate™ and Philips CX50 ultrasound consoles. The ViewFlex™ Xtra Reprocessed Reprocess Catheter has been reprocessed by Abbott one (1) time. Each catheter includes marking on the proximal handle and connector that identify the catheter status. Device is taken out of service after reaching the maximum number of reprocessing cycles. Abbott restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.
Model Number	D087031-R
Indication For Use	The ViewFlex™ Xtra Reprocessed ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

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 claims, clinical applications, patient populations, or performance specifications. The subject device is reprocessed 1 time (1X) after clinical use of the predicate device. Abbott's reprocessing includes removal of visible soil and decontamination. Each device is inspected and functionally tested prior to packaging, labeling and sterilizing. The differences between the ViewFlex™ Xtra Reprocessed ICE Catheter and the predicate device does not raise any new questions of safety and effectiveness.
Functional and Safety Testing	Design verification activities were performed with their respective acceptance criteria to ensure that the 1X reprocessing from the clinically used ViewFlex™ Xtra ICE Catheter does not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. **Testing** The ViewFlex™ Xtra Reprocessed ICE Catheter was developed and tested in accordance with the following industry guidance documents and standards: – Guidance for Industry and FDA staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices – EN ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices **Types of Testing Performed** – Cleaning Validation – Biocompatibility – Sterilization – Design validation – Design verification – Packaging verification
Conclusion	The technological characteristics for the subject device, and the indications for use are the same as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device have been demonstrated to be substantially equivalent.

The following device is included in the scope of this 510(k) submission:

Description	Reference Model Number (Predicate)	Reprocessed Model Number (Subject)	Usable Length	French Size	System Compatibility
ViewFlex™ Xtra Reprocessed ICE Catheter	D087031	D087031-R	90cm	9F	ViewMate™ Z ViewMate™ Philips CX 50