July 25, 2023

Stryker Sustainability Solutions
Mia Brown
Staff Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

Re: K231621
Trade/Device Name: Reprocessed ViewFlex Xtra ICE Catheter (D087031)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: June 2, 2023
Received: June 2, 2023

Dear Mia Brown:

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,

Marco Cannella -S

for

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 model number included in the scope of this submission is as follows:

Model Number	Description	Usable length	French size
D087031	Reprocessed ViewFlex Xtra ICE Catheter	90cm	9F

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.

Submission Number *(if known)*

K231621

Device Name

Reprocessed ViewFlex Xtra ICE Catheter (D087031)

Indications for Use *(Describe)*

The Reprocessed 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Name and Address: Stryker Sustainability Solutions
1810 W. Drake Drive
Tempe, Arizona 85283

Contact Name and Address: Mia Brown
Staff Regulatory Affairs Specialist
480-343-1855 (c)
480-763-2965 (f)
mia.brown1@stryker.com

Date of Preparation: June 2, 2023

Device Information:

Trade/Proprietary Name: Reprocessed ViewFlex Xtra ICE Catheter

Common Name: Diagnostic Intravascular Catheter

Classification Name: Reprocessed Intravascular Ultrasound Catheter

Regulation Number: Cardiovascular (21 CFR § 870.1200, Class II)

Product Code: OWQ

Model Number: D087031

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
D087031	K182238	Reprocessed ViewFlex Xtra ICE Catheter	Stryker Sustainability Solutions
D087031	K133853	ViewFlex Xtra ICE Catheter	Irvine Biomedical, Inc. a St. Jude Company

Device Description:

The Reprocessed ViewFlex Xtra ICE Catheter is a temporary intracardiac ultrasound catheter intended for use in patients to visualize cardiac structures and blood flow within the heart. The Reprocessed ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The Reprocessed ViewFlex Xtra ICE Catheter shaft is a 9 French catheter 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 housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the catheter has two deflection mechanisms that correspond with movement of the distal shaft in the four planes of movement.

The Reprocessed ViewFlex Xtra Ice Catheter is compatible with ViewMate II, ViewMate Z or ViewMate and Philips CX50 ultrasound consoles via the use of a compatible ViewFlex Catheter interface module.

The model number included in the scope of this submission is as follows:

Model Number	Description	Usable length	French size
D087031	Reprocessed ViewFlex Xtra ICE Catheter	90cm	9F

Intended Use:

The Reprocessed 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.

Technological Comparison:

The design, materials, and intended use of the Reprocessed ViewFlex Xtra ICE Catheter are equivalent to the predicate and reference devices. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of the device includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations. This 510(k) adds a second reprocessing cycle to the same device cleared under K182238.

Functional and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed ViewFlex Xtra ICE Catheter, including:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Performance Testing
    - Visual Inspection
    - Simulated Use
    - Dimensional Verification
    - Ultrasound Transducer Testing
    - Image Quality Testing
    - Acoustic Output Testing
    - Mechanical Characteristics
- EMC and Electrical Safety Testing

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

The Reprocessed ViewFlex Xtra ICE Catheter is reprocessed no more than two (2) times. Each reprocessed device is tracked with a serial number label which is affixed to the catheter shaft. Once the device reaches the maximum number or reprocessing cycles, it is rejected and taken out of service. Reprocessing is conducted only by Stryker Sustainability Solutions. Stryker Sustainability Solutions restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:

The results of bench and laboratory testing demonstrate that the subject device is at least as safe and effective as the predicate device.