November 20, 2020

Innovative Health, LLC.
Amanda Babcock
Regulatory Affairs Manager
435 North Hayden Road Suite 100
Scottsdale, Arizona 85257

Re: K202042
Trade/Device Name: Reprocessed ViewFlex Xtra Ice Diagnostic Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: October 19, 2020
Received: October 20, 2020

Dear Amanda Babcock:

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,

Mark Fellman
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 item numbers in scope of this submission are as follows:

| REF Item Number | Catalog/Reorder Item Number | Description | Sheath Usable Length (cm) | French Size | System Compatibility |
|---|---|---|---|---|---|
| D087031 | 100046963 | ViewFlex Xtra ICE Diagnostic Ultrasound Catheter | 90 | 9F | St. Jude Medical ViewMate, ViewMate II, ViewMate Z Console/Phillips CX50 |

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)*

K202042

Device Name
Reprocessed ViewFlex Xtra ICE Diagnostic Ultrasound Catheter

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.

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## SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92(c)

**Submitter's Name and Address:**
Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257

**Contact Name and Information:**
Amanda Babcock
Regulatory Affairs Manager
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

**Date prepared:**
November 19, 2020

**Device Information:**

| | |
|---|---|
| *Trade/Proprietary Name:* | Reprocessed ViewFlex Xtra ICE Diagnostic Ultrasound Catheter |
| *Common Name:* | ICE Catheter |
| *Classification Name:* | Reprocessed Intravascular Ultrasound Catheter |
| *Classification Number:* | Class II, 21 CFR 870.1200 |
| *Product Code:* | OWQ |

**Predicate Device:**

| 510(k) Number | Device | Manufacturer |
|---|---|---|
| K173262 | Reprocessed ViewFlex Xtra ICE Diagnostic Ultrasound Catheter | Innovative Health, LLC. |
| K133853 | ViewFlex Xtra ICE Catheter | Irvine Biomedical, Inc. a St. Jude Medical Company |

**Device Description:**
The Reprocessed ViewFlex Xtra ICE 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.

The item numbers in scope of this submission are as follows:

| REF Item Number | Catalog/Reorder Item Number | Description | Sheath Usable Length (cm) | French Size | System Compatibility |
|---|---|---|---|---|---|
| D087031 | 100046963 | ViewFlex Xtra ICE Diagnostic Ultrasound Catheter | 90 | 9F | St. Jude Medical ViewMate, ViewMate II, ViewMate Z Console/Phillips CX50 |

Table 5.1: Device Scope

This 510(k) adds a second reprocessing cycle to the same device cleared under K173262 and minor changes to the reprocessing and sterilization release method.

**Indications for 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 Characteristics:**
The purpose, design, materials, function, and intended use of the Reprocessed Diagnostic Ultrasound Catheters are identical to the predicate devices. There are no changes to the claims, clinical applications, patient populations, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of the Diagnostic Ultrasound Catheter includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

**Functional and Safety Testing:**
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Diagnostic Ultrasound Catheters. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Ultrasound Transducer Testing
    - Simulated Use
    - Mechanical Characteristics
- Packaging Performance Validation
- Electrical Safety Testing
    - Dielectric and Current Leakage

The Reprocessed Diagnostic Ultrasound Catheters are reprocessed no more than two (2) times. Each device is marked and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing. Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

**Predicate Comparison:**
A comparison of the device and reprocessing methods with the predicates are provided in the table below:

| | K202042 | K173262 | K133853 |
|---|---|---|---|
| Device: | Identical | Identical | Identical |
| Reprocessing Cycles: | 2 | 1 | 0 |
| Reprocessing Method: | Change to processing parameters to accommodate increase in batch size. Packaging configuration change. | Cleared/validated process | N/A |
| Sterilization: | Change to release method. No change to the sterilization method or SAL. | Cleared/validated process | N/A |
| Routine Monitoring: | Change to frequency and adjustment of limits. | Cleared process | N/A |

**Conclusion:**
Innovative Health concludes that the Reprocessed Diagnostic Ultrasound Catheter is as safe and effective as the predicate devices described herein.