



March 6, 2018

Innovative Health, LLC.
Amy Stoklas-Oakes
Director, Quality and Regulatory
1435 North Hayden Road
Suite 100
Scottsdale, Arizona 85257

Re: K173262

Trade/Device Name: Reprocessed ViewFlex Xtra Ice Diagnostic Ultrasound Catheter
(See enclosed list for model numbers)

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic Intravascular Catheter

Regulatory Class: Class II

Product Code: OWQ

Dated: February 1, 2018

Received: February 5, 2018

Dear Amy Stoklas-Oakes:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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

REF Item Number	Catalog 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 1: Devices in Scope

Indications for Use

510(k) Number (if known)

K173262

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:

Amy Stoklas-Oakes
 Director, Quality and Regulatory
 Innovative Health, LLC.
 (480) 525-5972 (office)
 (888) 965-7705 (fax)
astoklas-oakes@innovative-health.com

Date prepared:

October 10, 2017

Device Information:

<i>Trade/Proprietary Name:</i>	Reprocessed ViewFlex Xtra ICE Diagnostic Ultrasound Catheters
<i>Common Name:</i>	ICE Catheter
<i>Classification Name:</i>	Reprocessed Intravascular Ultrasound Catheter
<i>Classification Number:</i>	Class II, 21 CFR 870.1200
<i>Product Code:</i>	OWQ

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
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

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
- Electrical Safety Testing
 - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed Diagnostic Ultrasound Catheters are reprocessed no more than one (1) time. 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.

Conclusion:

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