November 14, 2019

Sterilmed, Inc.
Jan Flegeau
Associate Director, Regulatory Affairs
5010 Cheshire Pkwy N, Suite 2
Plymouth, Minnesota 55446

Re: K190478
Trade/Device Name: Reprocessed ViewFlex™ Xtra ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: October 9, 2019
Received: October 10, 2019

Dear Jan Flegeau:

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,

Nicole Gillette
Assistant Director (Acting)
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 model is included in the scope of this 510(k) submission:

Model Number	**Descxription**	**Useable Length**	**French Size**
D087031	Reprocessed ViewFlex™ Xtra ICE Catheter	90 cm	9F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190478

Device Name
Reprocessed ViewFlex™ Xtra ICE 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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510(K) SUMMARY

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

Date Prepared:	November 14, 2019
Submitter and Manufacturer:	Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446 www.sterilmed.com
Manufacturing Facility Address:	11400 73rd Avenue North Maple Grove MN 55369
Official Correspondent:	Jan Flégeau Associate Director, Regulatory Affairs Sterilmed, Inc. Tel: 786-575-5903 Email: jflegeau@its.jnj.com
Trade Name:	Reprocessed ViewFlex™ Xtra ICE catheter
Regulation Name:	Diagnostic Intravascular Catheter
Device Classification:	Class II
Product Code	OWQ
Predicate Device:	ViewFlex™ Xtra ICE Catheter (K133853)
Device Description:	The Reprocessed ViewFlex™ Xtra 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 Reprocessed ViewFlex™ Xtra ICE catheter has a useable length of 90 cm, with a 9 French (F) shaft with an ultrasound transducer. A10F 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.

<table>
<tr><td></td><td>The reprocessed ViewFlex™ Xtra ICE catheter is compatible with the ultrasound consoles listed in the table below. See table below for specifics on each ultrasound console.
<table>
<tr><th>Compatible Ultrasound Console*</th><th>ViewMate™ II</th><th>ViewMate™ Z or ViewMate™</th><th>Philips CX50[a]</th></tr>
<tr><td>Compatible ViewFlex™ Catheter Interface Module</td><td>100038191</td><td>H701374
100043720</td><td>H701375
H700296</td></tr>
<tr><td>Maximum Viewing Depth</td><td>18 cm</td><td>18 cm</td><td>18 cm</td></tr>
</table>
*All consoles are not available in all countries.</td></tr>
<tr><td>Model Number</td><td>RD087031</td></tr>
<tr><td>Indications For Use:</td><td>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.</td></tr>
<tr><td>Technological Characteristics:</td><td>The Reprocessed ViewFlex™ Xtra ICE catheter has the same technological and performance characteristics as the predicate device (K133853). The catheter is connected to a compatible ultrasound console via the appropriate Catheter Interface Module (CIM). Clinically, these devices are most often inserted into a vein and advanced into the heart. A small incision is made in the skin, usually in the groin or neck area, then a needle and introducer sheath are used to puncture the vein. The catheter is inserted and manipulated through the sheath into the vein until appropriately positioned. The ultrasound transducer on the tip of the catheter is then used to visualize cardiac structures, blood flow and other devices within the heart.</td></tr>
<tr><td>Functional and Safety Testing:</td><td>Representative samples of reprocessed devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced. The reprocessed ViewFlex™ Xtra ICE catheter is marked and tracked through the reprocessing cycle. After the device has been reprocessed one (1) time, it is rejected from further reprocessing.</td></tr>
<tr><td>Summary of Non-Clinical Tests Conducted:</td><td>Specific non-clinical tests performed included: cleaning validation, sterilization verification, ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf-life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, and fatigue testing.</td></tr>
</table>

	Testing performed: • Electrical Leakage • Torsional Strength • Flexation Fatigue • Fluid Integrity • Joint Bond Strength • Deflection Fatigue • Stiffness • Tip Buckling • Transducer Sensitivity • Ultrasound console compatibility • Acoustic Output • Thermistor Functionality Performance testing shows the reprocessed ViewFlex™ Xtra ICE catheter to perform as originally intended. In addition, the device was tested for biocompatibility per ISO 10993-1 for external communicating device, short duration contact with circulating blood (<24 hours). Biocompatibility testing included: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity • Hemocompatibility • Thrombogenicity
Conclusion:	Sterilmed conducted performance testing (described above) for the Reprocessed ViewFlex™ Xtra ICE catheter against the OEM predicate device, ViewFlex™ Xtra ICE catheter (K133853). Results demonstrated substantial equivalence to the predicate devices and does not raise different questions in safety or effectiveness. Sterilmed therefore concludes that the Reprocessed ViewFlex™ Xtra ICE catheter is substantially equivalent to the predicate device, ViewFlex™ Xtra ICE catheter.

The following device is included in the 510(K) submission:

Device Name	OEM Model Number	Sterilmed Catalog Number	System Compatibility
Reprocessed ViewFlex™ Xtra ICE Catheter	D087031	RD087031	ViewMate™ II
			ViewMate™ Z
			ViewMate™
			Philips CX50