DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2016

Sterilmed, Inc.
% Ming Chew
Regulatory Consultant
Libra Medical Inc.
8401 63rd Avenue North, Suite 63
Brooklyn Park, Minnesota 55428

Re: K152090
Trade/Device Name: Reprocessed Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: February 25, 2016
Received: February 26, 2016

Dear Ming Chew:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment

The following models are included in the clearance of K152090:

G408318
G408319
408309
408310
G408324

5. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
510(k) Number (*if known)*	
K152090	
Device Name	
Reprocessed Steerable Introducers	
Indications for Use (*describe*)	
The reprocessed steerable introducer devices are indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	
Type of Use (*select one or both, as applicable)*	
☒ Prescription Use (Part 21 CFR 801 Subpart D)	☐ Over-The-Counter Use (Part 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 EMAL 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."*	

1. 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

1.1.1 Sponsor

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1.2 DEVICE NAME

Trade Name	Reprocessed Steerable Introducer
Common Name	Steerable Introducer
Classification Name	Reprocessed Catheter Introducer
Classification	II
Primary Product Code	PNE

1.3 DEVICE DESCRIPTION OVERVIEW

The reprocessed steerable introducer consists of a steerable sheath and plastic dilator, which is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The device is always delivered over a guidewire. The steerable introducer device enters through the right femoral vein and is guided into the right atrium of the heart. A knob on the introducer handle dictates the amount and direction of curl at the distal tip of the sheath. The shaft of the introducer is filled with radiopaque material so the device can be seen using fluoroscopy. A guidewire pokes through the septum into the left atrium and a tapered dilator enlarges the hole. The dilator is then removed allowing the introduction of a catheter.

Note: The guidewire is not included in the scope of this submission as it is purchased off-the-shelf (K935170) and packaged with the reprocessed devices. Only the steerable sheath and plastic dilator are subject in this submission. In this submission references to the "device(s)" refers to both the sheath and dilator.

1.4 INDICATIONS FOR USE

The Reprocessed Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

1.5 TECHNOLOGY OVERVIEW

The device is an 8.5F asymmetrical bi-directional steerable introducer with a varying amount of curl (small, medium or large) at the distal tip and a useable length of 61 or 71 cm. The proximal end of the device sheath is fitted with a hemostasis valve to minimize blood loss during catheter insertion and/or exchange over a guidewire. A side port with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. A handle is equipped with a rotating collar to deflect the large curl 90 ° in the counterclockwise direction and 180˚ in the clockwise direction. The sheath is filled with radiopaque material for visualization under fluoroscopy.

1.6 PERFORMANCE TESTING OVERVIEW

The reprocessed steerable introducer devices are substantially equivalent to the new un-reprocessed predicate devices (K061363 and K081645) in that the reprocessed devices are the same as the new un-reprocessed predicate devices in terms of form, fit, function, and intended use. No animal or clinical testing was conducted for this premarket notification submission. Physical and performance testing included:

- Cap Retention
- Shaft Deflection and Flexation
- Joint Strength
- Leak

- Shaft Torque
- Stiffness
- Distribution
- Torque Response
- Dimensional Verification
- Systems Use

In addition, the device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). Biocompatibility testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatability
- Thrombogenicity
- Chemical Pyrogens
- Hemolysis
- Immune Response

The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device.

1.7 SUBSTANTIAL EQUIVALENCE

Sterilmed's reprocessed steerable introducer devices are substantially equivalent to the predicate devices, St. Jude Agilis™ NxT Steerable Introducers. There are no changes to the clinical applications, patient population, performance specifications, or method of operation. The reprocessing does not change the design or function of the device, but restores the performance characteristics of a used device. After reprocessing, the devices are identical in form, fit, functionality and intended use as the predicate devices (K061363 and K081645).

1.8 CONCLUSION

The reprocessed steerable introducer devices have identical indications for use and technological characteristics as the predicate devices. Functional testing has shown the reprocessing does not affect the performance of the devices, nor the safety of the devices. Therefore, the reprocessed steerable introducer devices and the predicate devices are substantially equivalent.