DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2016

Sterilmed, Inc.
Neelu Gibson
Senior Director, Regulatory Affairs
5010 Cheshire Parkway, Suite 2
Plymouth, Minnesota 55446

Re: K161700
Trade/Device Name: Reprocessed 3D Diagnostic Ultrasound eco Catheters (See attached list of models)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: October 7, 2016
Received: October 11, 2016

Dear Neelu Gibson:

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,

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

Enclosure

K161700

Models intended for reprocessing

Original Manufacturer	OEM Model Number	Reprocessed Product Code	Description
Biosense Webster, Inc.	10439011	R10439011	SoundStar® eco Diagnostic Ultrasound Catheter, 8F, 90 cm length. For use with Siemens ultrasound systems.
Biosense Webster, Inc.	10439236	R10439236	SoundStar® eco Diagnostic Ultrasound Catheter, 8F, 90 cm length. For use with GE ultrasound systems.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161700

Device Name
Reprocessed 3D Diagnostic Ultrasound eco Catheters

Indications for Use *(Describe)*
The Reprocessed 3D Diagnostic Ultrasound eco Catheters are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible Carto® 3 EP Navigation Systems (version 2.3 and higher) the reprocessed 3D Diagnostic Ultrasound eco Catheters provide location information.

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.

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STERILMED

510(k) Summary - K161700

Submitter and Manufacturer:	Neelu Gibson Sterilmed, Inc. 5010 Cheshire Parkway, Suite 2 Plymouth, MN 55446
Manufacturing Facility Address:	11400 73rd Avenue North Maple Grove, MN 55369
Primary Contact:	Neelu Gibson Sterilmed, Inc. Tel: 908-705-3160 Fax: 763-488-3350 Email: ngibson9@its.jnj.com
Date of Submission:	21 May, 2016
Trade Name:	Reprocessed 3D Diagnostic Ultrasound eco Catheters
Regulation Name:	Diagnostic Intravascular Catheter
Device Classification:	Class II
Product Code:	OWQ

Predicate Device:	Biosense Webster, Inc.: SoundStar eco 8F G Ultrasound Catheter, and SoundStar eco 8F Ultrasound Catheter (510(k) K140318)
Secondary / Reference Predicates	Sterilmed Inc: Reprocessed 3D Ultrasound Diagnostic Catheter (510(k) K110076) Sterilmed Inc: Reprocessed Ivus Imaging Catheter (510(k) K043453)
Device Description:	Sterilmed Reprocessed 3D Diagnostic Ultrasound eco Catheters are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer and three-dimensional location sensor. They are IntraCardiac Echo (ICE) Catheters with acoustic array and magnetic location sensor equivalent to the currently cleared SoundStar eco 8F G Ultrasound Catheter, and SoundStar eco 8F Ultrasound Catheters 510(k) K140318. The magnetic location sensor (providing location information to the CARTO® 3 EP Navigation System) and an ultrasound transducer (acquiring real time ultrasound images) are embedded in the catheter tip. The Reprocessed 3D Diagnostic Ultrasound Catheters, when connected to the corresponding Ultrasound Systems, will provide real-time integration of the ultrasound images with CARTO® 3 electromagnetic acquired maps. Note: Only the catheter is the subject of this submission. Accessories and/or any other related equipment are not included in the scope of this submission. The table below lists the specific model numbers that are the subject of this submission.

<table>
<tr><td></td><td>
<table>
<tr><th>Original Manufacturer</th><th>OEM Model Number</th><th>Reprocessed Product Code</th><th>Description</th></tr>
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</table>
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<tr><td>Technological Characteristics:</td><td>The Reprocessed 3D Diagnostic Ultrasound eco Catheters are identical to the predicate devices in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.</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.
Where appropriate prior validation testing of previously cleared Reprocessed 3D Diagnostic Ultrasound eco Catheter K110076 and Reprocessed AcuNav Imaging Catheter K043453 was utilized for the same reprocessing procedures, equipment, sterile barrier and sterilization processing. The Reprocessed 3D Diagnostic Ultrasound eco Catheters are reprocessed no more than three (3) times. Each device is marked and tracked through each reprocessing cycle. After the device has reached the maximum number of reprocessing cycles (3), the device is rejected from further reprocessing. Reprocessing is performed only by the manufacturer Sterilmed, Inc.</td></tr>
<tr><td>Summary of Non-Clinical Tests Conducted:</td><td>Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf life validation (ASTM 1980-99). In addition, functional performance (including both the ultrasound and 3D location sensor components) and mechanical reliability were validated using bench and laboratory testing.
Performance testing shows the Reprocessed 3D Diagnostic Ultrasound eco</td></tr>
</table>

	Catheters perform as originally intended.
Conclusion:	Sterilmed concludes that the Reprocessed 3D Diagnostic Ultrasound eco Catheters are safe, effective, and substantially equivalent to the predicate devices, Biosense Webster, Inc. SoundStar eco 8F and eco 8F G Ultrasound Catheters (K140318), as described in this premarket notification submission. The Reprocessed 3D Diagnostic Ultrasound eco Catheters are substantially equivalent to the listed predicate devices with respect to their indications for use (intended use) and technical characteristics. The information and data provided in this 510(k) submission identify no new safety or effectiveness issues.

Summary of Performance Testing

Verification Testing	Description	Pass/ Fail
Joint Bond Strength (SM5653/5840)	Test measured tensile strength of device joints to confirm reprocessing has no effect on device.	Pass
Torsional Strength (SM5652/5842)	Test measured the torsional strength of the flexible tip and shaft sections to confirm reprocessing has no effect on device.	Pass
Flexation Fatigue (SM5604/5827)	Test measured flexation through maximum range of deflection 100 times to confirm that reprocessing has no effect on device.	Pass
Deflection Fatigue (SM5605/5823)	Testing measured deflection in a simulated use model through full articulation multiple times to confirm that reprocessing has no effect on device.	Pass
Tip buckling (SM4091/5923)	Testing measured force required to cause tip buckling, to ensure reprocessing has effect on device.	Pass
CCS check (SM5523/5822)	Calibration check testing confirmed that reprocessing has no effect on device's ability to maintain sensor location.	Pass
Auto ID (SM5800/5830)	Testing confirmed that reprocessed devices continue to be identified as Soundstar eco 8F catheters	Pass
EEPROM reset verification (SM5802/5841)	Testing confirmed that EEPROM can be effectively reset and continue to function as intended on reprocessed devices.	Pass
AMCS Acoustic Verification (SM5522/5828)	Testing confirmed that Acoustic Manual Calibration System functions for reprocessed devices.	Pass
Thrombogenicity testing SM6020/6828	Testing confirmed that reprocessed devices do not cause any new risk of thrombus formation.	Pass

- **Biocompatibility testing**

  Biocompatibility data demonstrates that there is no risk presented by Reprocessed SoundStar eco 8F and eco 8F G Ultrasound Catheters.

- **Electromagnetic compatibility (EMC) testing** was performed by Sterilmed per IEC 60601-1:2005 AI:2012 3rd Edition Medical electrical equipment – Part 1 General requirements for basic safety and essential performance were the defibrillation, leakage current and functional testing.

  Defibrillation
  Test report SM 5839 documents the defibrillation protection compliance to the IEC 60601-1:2005 Clause 8.5.5.1 for defibrillation protection testing.
  IEC 60601-1:2005 Clause 8.5.5.1 for defibrillation protection testing defines a peak value of the differential signal (Yl -Y2) to be less than 1 volt (passing the test). Voltage reading over 1 volt is considered a fail.

  Current Leakage and Functional Test
  To mitigate the concerns of possible damage to the device due to reprocessing the devices are:
  - 100% in-process inspected for electrical insulation via Hi-pot (high potential) testing, in which each device is subjected to 1500VDC, and electrical leakage is monitored. Reference test report SM5831
  - 100% in-process inspected for functionality.

  IEC 60601-1-2:2007
  No physical changes or parts replacement is conducted by Sterilmed during the reprocessing. The devices are unchanged and are identical to the OEM devices as evidenced in functional tests SM5828 - AMCS Check - SoundStar eco 8F within Error! Reference source not found..

  IEC 61161:2013
  Total emitted acoustic power of ultrasonic transducers was verified and documented in SM5826.

Summary

The Reprocessed 8F Catheters and their predicate devices, the OEM 8F Catheters, have the same intended use and indications for use and fundamental scientific technology. Based on performance testing for the Reprocessed 8F Catheters against the OEM devices discussed above, Sterilmed concludes that the Reprocessed 8F catheters are safe, effective, and substantially equivalent to the predicate OEM 8F catheters.