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

June 23, 2016

Sterilmed, Inc.
Patricia Kaufman
Regulatory Affairs Specialist
5010 Cheshire Parkway, Suite 2
Plymouth, Minnesota 55446

Re: K153006
Trade/Device Name: Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Catheter Electrophysiology (EP) Catheters
(See attached list of models)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: May 23, 2016
Received: May 24, 2016

Dear Patricia Kaufman:

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.

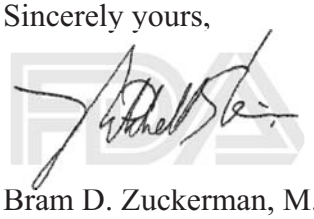
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

K153006

MODELS INTENDED FOR REPROCESSING

	Catheter Model	Poles	Loop		Curve	Electrode Spacing (mm)	Shaft	
			Diameter (mm)	Profile (F)			Profile (F)	Length (cm)
LASSO® 2515 NAV eco Variable Catheter								
1	**D134301**	20	25 – 15	4	D	2 – 6 – 2	7	115
2	**D134302**	10	25 – 15	4	D	8	7	115
LASSO® NAV eco Catheter								
3	**D134901**	10	15	4.5	D	4.5	7	115
4	**D134902**	20	15	4.5	D	4.5 pairs	7	115
5	**D134903**	10	20	4.5	D	6.0	7	115
6	**D134904**	20	20	4.5	D	6.0 pairs	7	115
7	**D134905**	10	25	4.5	D	8.0	7	115
8	**D134906**	20	25	4.5	D	8.0 pairs	7	115
9	**D134909**	10	20	4.5	D	6.0	7	115

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)*
K153006

Device Name
Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters

Indications for Use *(Describe)*
The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. stimulation and recording only. The catheters are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters with navigation (Nav) capabilities provide location information when used with compatible Carto® 3 EP Navigation Systems. (These catheters are not compatible with Carto® 3 EP Navigation Systems prior to version 2.3.)

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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2. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Sterilmed, Inc. 5010 Cheshire Pkwy N, Suite 2 Plymouth, MN 55446 www.sterilmed.com Tel: (888) 541-0078
OFFICIAL CORRESPONDENT	Patricia F. Kaufman Sterilmed, Inc. 5010 Cheshire Pkwy N, Suite 2 Plymouth, MN 55446 pkaufman@sterilmed.com Tel: (763) 488-3211 Fax: (763) 488-3350
DATE PREPARED	12 October 2015
TRADE NAME	Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters
COMMON NAME	Electrophysiology Diagnostic Catheters
510(K) NUMBER	K153006
DEVICE CLASSIFICATION	Name: Catheter, Recording, Electrode, Reprocessed Regulation No: §870.1220 Product Code: NLH Class: II Panel: Cardiovascular
PREDICATE DEVICE	Lasso 2515 NAV *eco* Variable Catheter, Lasso NAV *eco* Catheter – K113213

SUBSTANTIALLY EQUIVALENT TO:

The Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters are substantially equivalent to the single use Biosense Webster Lasso 2515 NAV *eco* Variable Catheter and Lasso NAV *eco* Catheter in intended use and technological features.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters are designed to facilitate electrophysiological mapping of the atria of the heart. They are deployed in the right or left atrium through an 8F guiding sheath. These deflectable catheters consist of a circular spine on the distal tip with platinum/iridium electrodes that can be used for stimulation and recording.

Models designated as NAV are compatible with the Carto® 3 EP Navigation System.

The following models are the subject of this submission:

	Catheter Model	Poles	Loop		Curve	Electrode Spacing (mm)	Shaft	
			Diameter (mm)	Profile (F)			Profile (F)	Length (cm)
LASSO® 2515 NAV eco Variable Catheter								
1	**D134301**	20	25 – 15	4	D	2 – 6 – 2	7	115
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8	**D134906**	20	25	4.5	D	8.0 pairs	7	115
9	**D134909**	10	20	4.5	D	6.0	7	115

INDICATIONS FOR USE:

The Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. stimulation and recording only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters with navigation (NAV) capabilities provide location information when used with compatible Carto® 3 EP Navigation Systems. (These catheters are not compatible with Carto® 3 EP Navigation Systems prior to version 2.3.)

TECHNICAL CHARACTERISTICS:

The Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) 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.

PERFORMANCE STANDARDS:

No applicable performance standards have been issued under 514 of the Food, Drug and Cosmetic Act for a Catheter, Recording, Electrode, Reprocessed §870.1220.

FUNCTIONAL AND SAFETY TESTING:

Representative samples of Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters 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 100% of products reprocessed. The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters are reprocessed no more than one (1) time. Each device is marked and tracked through each reprocessing cycle. After the device has reached the maximum number of reprocessing cycles (1), the device is rejected from further reprocessing. Reprocessing is performed only by the manufacturer Sterilmed.

SUMMARY OF NONCLINICAL TESTING:

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 D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM F 1980). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the Reprocessed LASSO NAV *eco* and Reprocessed LASSO 2515 NAV *eco* Variable Electrophysiology (EP) Catheters to perform as originally intended.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Sterilmed concludes that the Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheters are safe, effective, and substantially equivalent to the predicate devices, Biosense Webster Lasso Catheters (K113213), as described in this premarket notification submission. The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) 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 identifies no new safety or effectiveness issues.