June 23, 2021

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

Re: K201806
Trade/Device Name: Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: NLG
Dated: May 20, 2021
Received: May 21, 2021

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,

Aneesh Deoras
Acting Assistant Director
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 models are included in the scope of this 510(k) submission:

Device Name	Biosense Webster Model Numbers	Sterilmed Model Numbers	Description
Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter	D128207	RD128207	7Fr, F Curve, 4-4-4 mm spacing, 115 cm
	D128208	RD128208	7Fr, F Curve, 2-6-2 mm spacing, 115 cm
	D128210	RD128210	7Fr, D Curve, 4-4-4 mm spacing, 115 cm
	D128211	RD128211	7Fr, D Curve, 2-6-2 mm spacing, 115 cm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201806

Device Name
Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter

Indications for Use *(Describe)*
The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter provides location information when used with compatible CARTO™ 3 EP Navigation Systems. This catheter is not compatible with CARTO™ 3 EP Navigation Systems prior to Version 3.x.

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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510(K) SUMMARY

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

Date Prepared:	June 21, 2021
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 Flegeau Associate Director, Regulatory Affairs Sterilmed, Inc. Tel: 786-575-5903 Email: jflegeau@its.jnj.com
Trade Name:	Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter
Regulation Name:	Catheter, Intracardiac Mapping, High-Density, Reprocessed
Common Name:	Deflectable Tip Electrophysiology Catheter-Diagnostic
Device Classification:	II
Product Code	NLG
Predicate Device:	PENTARAY® NAV eco High-Density Mapping Catheter (Biosense Webster K123837)
Device Description:	The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter is designed to facilitate electrophysiological mapping of the heart with the CARTO® 3 EP Navigation System. It is designed for deployment in a heart chamber through an 8 Fr guiding sheath. This deflectable catheter consists of multiple 3 Fr spines on the distal tip, each spine having multiple platinum electrodes that are used for stimulation and recording. A magnetic location sensor embedded in the deflectable tip transmits location information to the CARTO® 3 EP Navigation System. The catheter has two electrodes on the deflectable tip to provide for visualization of the tip when used with the CARTO® 3 EP Navigation System. Pushing forward on the catheter thumb knob deflects the tip; pulling back on the thumb knob straightens the tip. This catheter includes an irrigation lumen for connection to a source of continuous drip anticoagulant fluid.

Model Numbers	RD128207	7Fr, F Curve, 4-4-4 mm spacing, 115 cm
	RD128208	7Fr, F Curve, 2-6-2 mm spacing, 115 cm
	RD128210	7Fr, D Curve, 4-4-4 mm spacing, 115 cm
	RD128211	7Fr, D Curve, 2-6-2 mm spacing, 115 cm
Indications For Use:	The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 3.x.	
Technological Characteristics:	The Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter family is a 7 Fr, multi-electrode electrophysiological mapping catheter designed for diagnostic electrogram mapping and pacing in all chambers (atria and ventricles) of the heart. The catheters have five flexible spines, each with four ring electrodes for a total of 20 electrodes. There are two different electrode spacing configurations (4-4-4 or 2-6-2mm) and two different curves (F or D) in order to accommodate different clinical situations. The tip of the shaft houses a Magnetic Location Sensor that provides magnetic location information when used with the CARTO® 3 EP Navigation System. In addition to the 20 spine electrodes, two additional Ring Electrodes are located near the tip of the shaft for a total of 22 ring electrodes that provide location information via Advanced Catheter Location (ACL) technology when used with the CARTO® 3 EP Navigation System.	
Functional and Safety Testing:	Representative samples of reprocessed devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate cleaning and sterilization as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced. The PENTARAY® NAV eco High-Density Mapping Catheter is reprocessed no more than one (1) time. The catheter is marked and tracked through the reprocessing cycle.	

Summary of Non-Clinical Tests Conducted:	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. Testing performed: • Electrical Resistance and Isolation • Electrical Leakage • Leak test • Planarity, Curvature and Spine Spacing • CCS Calibration • Auto ID/EEPROM Reset Verification • Connector Cycling • Tip Stiffness • Tip Side Force • Tip Buckle • Fluid Integrity • Deflection Fatigue • Torsional Strength • Flexation Fatigue • Shaft Rotation Fatigue • Shaft and Connector Bond Strength • Micro Lumen Inspection • Final Rinse and blow out Performance testing demonstrates that the Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter performs 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 • Hemocompatibility • Thrombogenicity • Pyrogenicity

Conclusion:	Sterilmed conducted performance testing for the Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter against the OEM predicate device, the PENTARAY® NAV eco High-Density Mapping Catheter (K123837). Results demonstrated substantial equivalence to the predicate device. Sterilmed therefore concludes that the Reprocessed PENTARAY® NAV eco High-Density Mapping Catheter is substantially equivalent to the predicate device, the PENTARAY® NAV eco High-Density Mapping Catheter.