October 11, 2024

Sterilmed, Inc.
Rachel Poltilove
Regulatory Affairs
5010 Cheshire Pkwy N, Suite 2
Plymouth, Minnesota 55446

Re: K240826
Trade/Device Name: Reprocessed DECANAV™ Electrophysiology Catheter; Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: September 10, 2024
Received: September 11, 2024

Dear Rachel Poltilove:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 S. Deoras -S

Aneesh Deoras
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 devices are included in the scope of this 510(k) premarket notification:

Device Name	Biosense Webster Model Numbers	Sterilmed Model Numbers	Description
Reprocessed DECANAV™ Electrophysiology Catheter	R7D282CT	RR7D282CT	D Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34
	R7F282CT	RR7F282CT	F Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34
Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter	D728260RT	RD728260RT	Large Curve 270, 7F, 110 cm, Electrodes: 20, SP: 2-9-3…61…3-9-3mm, Tip Length: 2mm, Pin Connector: 10

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240826

Device Name
Reprocessed DECANAV™ Electrophysiology Catheter
Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter

Indications for Use *(Describe)*
The Reprocessed DECANAV™ Electrophysiology Catheter is indicated for electrophysiological mapping of cardiac structures i.e., recording and stimulation, including in the Coronary Sinus. In addition, the Reprocessed DECANAV™ Catheter is used with compatible Carto® 3 EP Navigation Systems to provide catheter tip location information.

The Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. In addition, the Reprocessed WEBSTER® Duo-Decapolar Catheter is designed to facilitate electrogram mapping in the atrial region of the heart and coronary sinus.

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.

510(k) Summary

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

Date Prepared:	October 11, 2024
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:	Dr. Rachel Poltilove Regulatory Consultant Sterilmed, Inc. Tel: 301-213-7224 Email: rpoltilo@its.jnj.com
Trade Name:	Reprocessed DECANAV™ Electrophysiology Catheter Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter
Classification Name:	Catheter, Recording, Electrode, Reprocessed
Common Name:	Diagnostic Electrophysiology Catheter
Device Classification:	Class II, 21 CFR 870.1220
Product Code	NLH
Primary Predicate Device:	Biosense Webster CS RefStar™ (DECANAV) Catheter (K080425)
Secondary Predicate Devices:	Biosense Webster CS RefStar™ (DECANAV) Catheter (K231312) Biosense Webster Duo-Decapolar Catheter (K101991)
Device Description:	The Reprocessed DECANAV™ Catheter is a sterile, single patient use device designed to be used with the CARTO® 3 EP Navigation System (a magnetic field location technology) to facilitate electrophysiological mapping of the heart. The catheter has a high torque shaft with a deflectable tip section containing an array of platinum/iridium electrodes that can be used for stimulation and recording of cardiac electrical signals. The Reprocessed DECANAV™ Catheter has a single proximal electrode that can be used for unipolar recording signals. The Reprocessed DECANAV™ Catheter tip deflection is controlled by a proximal hand piece that features a thumb operated sliding piston and is offered in curve

<table>
<tr><td></td><td>types D and F. Pushing the thumb knob forward causes the catheter tip to bend (curve); when the knob is pulled back, the tip straightens. The plane of the curved tip can be rotated during use. The Reprocessed DECANAV™ Catheter interfaces with standard recording equipment and CARTO® 3 EP Navigation System equipment via interface cables with the appropriate connectors.

The Reprocessed WEBSTER® Duo-Decapolar Catheter (DDP) is a sterile, single patient use device designed to facilitate electrophysiological mapping of the heart. The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum electrodes that can be used for stimulation and recording. Tip deflection is controlled at the proximal end by a tubular handpiece in which a piston slides. When the piston is pushed forward with the thumb knob, the tip is deflected (curved). When the piston is pulled back, the tip straightens. The high torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. The catheter interfaces with standard recording equipment via interface cables with the appropriate connectors.</td></tr>
<tr><td>Model Numbers</td><td><table>
<tr><td>RR7D282CT</td><td>Reprocessed DECANAV™ Electrophysiology Catheter, D Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34</td></tr>
<tr><td>RR7F282CT</td><td>Reprocessed DECANAV™ Electrophysiology Catheter, F Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34</td></tr>
<tr><td>RD728260RT</td><td>Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter, Large Curve 270, 7F, 110 cm, Electrodes: 20, SP: 2-9-3…61…3-9-3mm, Tip Length: 2mm, Pin Connector: 10</td></tr>
</table></td></tr>
<tr><td>Indications For Use:</td><td>The Reprocessed DECANAV™ Electrophysiology Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., recording and stimulation, including in the Coronary Sinus. In addition, the Reprocessed DECANAV™ Catheter is used with compatible Carto® 3 EP Navigation Systems to provide catheter tip location information.

The Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter is indicated for electrophysiological mapping of cardiac structures, i.e., stimulation and recording only. In addition, the Reprocessed WEBSTER® Duo-Decapolar Catheter is designed to facilitate electrogram mapping in the atrial region of the heart and coronary sinus.</td></tr>
</table>

Technological Characteristics:	The design, materials, function, and intended use of the Reprocessed DECANAV™ and Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheters are the same as that of the predicate devices. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation.
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 Reprocessed DECANAV™ and Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheters are reprocessed no more than one (1) time. The catheters are marked and tracked through the reprocessing cycle. After the devices have reached the maximum number of reprocessing cycles, the devices are rejected from further reprocessing. It is Sterilmed's policy to restrict its reprocessing to exclude devices previously reprocessed by other reprocessors.
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: • Joint Bond Strength • Torsional Resiliency • Tip Buckle • Fluid Integrity • Deflection Cycling • Flexation Cycling • Shaft Stiffness • Electrical Continuity • Electrical Leakage • Electrical Connector Cycling • Cable to Handle Retention Strength • CARTO® 3 System Compatibility of Duo-Decapolar

	• CARTO® 3 System Recognition of DECANAV • Electrical Resistance and Isolation • Coronary Sinus Handling Performance testing shows the Reprocessed DECANAV™ and Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheters perform as originally intended. In addition, the devices were 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 including Thrombogenicity, Hemolysis, and Complement Activation
Conclusion:	Sterilmed conducted performance testing for the Reprocessed DECANAV™ and Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheters against the OEM predicate devices, Biosense Webster CS RefStar™ (DECANAV) Catheter (K080425 & K231312) and Biosense Webster Duo-Decapolar Catheter (K101991). Results demonstrated substantial equivalence to the predicate devices. Based on testing results, the Reprocessed DECANAV™ and Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheters are substantially equivalent to the predicate devices, the Biosense Webster CS RefStar™ (DECANAV™) Catheter and the Biosense Webster Duo-Decapolar Catheter.

The following devices are included in the scope of this 510(k) submission:

Device Name	Biosense Webster Model Numbers	Sterilmed Model Numbers	Description
Reprocessed DECANAV™ Electrophysiology Catheter	R7D282CT	RR7D282CT	D Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34
	R7F282CT	RR7F282CT	F Curve, 7F, 115cm, Electrodes: 11, SP: 2-8-2mm, Tip Length: 2.4mm, Pin Connector: 34
Reprocessed WEBSTER® Duo-Decapolar Electrophysiology Catheter	D728260RT	RD728260RT	Large Curve 270, 7F, 110 cm, Electrodes: 20, SP: 2-9-3…61…3-9-3mm, Tip Length: 2mm, Pin Connector: 10