June 29, 2026

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

Re: K254149
Trade/Device Name: Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System (R11510825); Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System (R11657484); Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System (R11510826); Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System (R11657485)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: June 7, 2026
Received: June 8, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for: MARCO CANNELLA -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	OEM Model Numbers	Sterilmed Model Numbers	Description
Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter	11510826	R11510826	Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System
	11657485	R11657485	Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System
Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter	11510825	R11510825	Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System
	11657484	R11657484	Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254149

Please provide the device trade name(s).

Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System (R11510826);
Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System (R11657485);
Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System (R11510825);
Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System (R11657484)

Please provide your Indications for Use below.

The Reprocessed SOUNDSTAR CRYSTAL Ultrasound Catheter is 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, the catheter provides location information. Refer to the Biosense Webster Compatibility Matrix Insert for compatible CARTO 3 Systems as each catheter is compatible with a specific version of the CARTO 3 System and is not backward compatible with previous versions of the CARTO 3 EP Navigation System.

The Reprocessed AcuNav CRYSTAL Ultrasound Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary for K254149

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

Date Prepared:	June 5, 2026
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:	Rachel Poltilove, PhD Associate Director, Regulatory Affairs Sterilmed, Inc. Tel: 301-213-7224 Email: rpoltilo@its.jnj.com
Trade Name:	Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter
Classification Name:	Reprocessed Diagnostic Ultrasound Catheter
Common Name:	Diagnostic Intravascular Catheter
Device Classification:	Class II, 21 CFR 870.1200
Product Code:	OWQ
Primary Predicate Device:	Biosense Webster SOUNDSTAR CRYSTAL™ Ultrasound Catheter (K240050)
Secondary Predicate Devices:	Siemens AcuNav CRYSTAL™ Ultrasound Catheter (K233270)
Device Description:	The Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter is a 9F sterile, single patient use, disposable imaging catheter. The distal end of the catheter has an ultrasound transducer providing 2-D imaging and a 3-D location sensor providing location information to compatible Carto® 3 EP Navigation Systems with ultrasound capability. A steering mechanism controls the image plane orientation by rotating both the catheter tip and the variable deflection. The Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter is a 9F sterile, single patient use, disposable imaging catheter. The distal end of the catheter has an ultrasound transducer providing 2-D imaging ultrasound capability. A steering mechanism controls the image plane orientation

<table>
<tr><td></td><td>by rotating both the catheter tip and the variable deflection. For ultrasound purposes, the Reprocessed AcuNav CRYSTAL™ and Reprocessed SOUNDSTAR CRYSTAL™ catheters are identical.

The Reprocessed SOUNDSTAR CRYSTAL™ and AcuNav CRYSTAL™ Ultrasound Catheters are reprocessed no more than one time. Each device is marked and tracked through the reprocessing cycle. After the device has been reprocessed once, it is rejected from further reprocessing. Sterilmed does not reprocess catheters that have previously been reprocessed by other 3rd party reprocessors.</td></tr>
<tr><td>Model Numbers:</td><td><table>
<tr><td>R11510826</td><td>Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System</td></tr>
<tr><td>R11657485</td><td>Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on GE System</td></tr>
<tr><td>R11510825</td><td>Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter 9F x 90 CM, For Use on Siemens System</td></tr>
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</table></td></tr>
<tr><td>Indications For Use:</td><td>The Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter is 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, the catheter provides location information. Refer to the Biosense Webster Compatibility Matrix Insert for compatible CARTO 3 Systems as each catheter is compatible with a specific version of the CARTO 3 System and is not backward compatible with previous versions of the CARTO 3 EP Navigation System.

The Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.</td></tr>
<tr><td>Technological Characteristics:</td><td>The technological characteristics of the Reprocessed SOUNDSTAR CRYSTAL™ Ultrasound Catheter including claims, clinical applications, patient population, performance specifications, and method of operation, are identical to the Biosense Webster SOUNDSTAR CRYSTAL™ Ultrasound Catheter.

The technological characteristics of the Reprocessed AcuNav CRYSTAL™ Ultrasound Catheter including claims, clinical applications, patient population, performance specifications, and method of operation, are</td></tr>
</table>

	identical to the Siemens AcuNav CRYSTAL™ Ultrasound Catheter.
Summary of Non-Clinical Tests Conducted:	The Reprocessed SOUNDSTAR CRYSTAL™ and AcuNav CRYSTAL™ Ultrasound Catheters have been evaluated for biocompatibility, cleanliness, sterilization, packaging, shelf life, and electrical, electromagnetic and mechanical safety, and have been found to conform with applicable medical device safety standards. The devices comply with the following voluntary standards: • ISO 14971, Application of Risk Management to Medical Devices • ANSI/AAMI ES 60601-1, Safety Requirements for Medical Equipment • ISO 10993-1, Biocompatibility • ISO 11135, Sterilization of Health-Care Products - Ethylene oxide • ISO 11607-1 and ISO 11607-2, Packaging for Terminally Sterilized Medical Devices Performance testing shows the Reprocessed SOUNDSTAR CRYSTAL™ and Reprocessed AcuNav CRYSTAL™ Ultrasound Catheters perform as originally intended.
Conclusion:	The Reprocessed SOUNDSTAR CRYSTAL™ and Reprocessed AcuNav CRYSTAL™ Ultrasound Catheters are substantially equivalent to their respective currently cleared predicate devices based on the successful completion of nonclinical bench testing as well as the technological comparison of identical principles of design, operation, and indications for use.