June 12, 2024

Biosense Webster, Inc.
Sheba Chacko
Senior Regulatory Affairs Program Lead
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K240050
Trade/Device Name: SOUNDSTAR™ CRYSTAL Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: May 31, 2024
Received: May 31, 2024

Dear Sheba Chacko:

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.

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

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.

Submission Number *(if known)*

K240050

Device Name

SOUNDSTAR™ CRYSTAL Ultrasound Catheter

Indications for Use *(Describe)*

The SOUNDSTAR™ CRYSTAL Ultrasound Catheter and related accessory devices 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, the catheter provides location information. Refer to the 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.

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 SMDA 1990 and 21 CFR 807.92

1.1 Submitter [21 CFR 807.92(a) (1)] and Device Information [21 CFR 807.92 (a) (2)]

Date Summary Prepared	May 30, 2024
Applicant	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618 Establishment Registration Number: 9044811
Official Correspondent	Sheba Chacko Senior Regulatory Affairs Program Lead Telephone: (949) 450-6058 Fax: (949) 450-6886
Trade Name	SOUNDSTAR™ Crystal Ultrasound Catheter
Common Name	Intracardiac Echocardiography Catheter
Classification Name	Diagnostic Intravascular Catheters
Device Classification	Class II, 21 CFR 870.1200
FDA Product Code	OBJ
Predicate device(s)	SOUNDSTAR eco 10F/10FG Ultrasound Catheter (K112050) AcuNav Crystal Ultrasound Catheter (K233270)

Table 1: Submitter Information

1.2 Predicate Device and Reference Device Information [21 CFR 807.92(a) (3)]

Predicate Device Information			
Predicate Device Name	**Manufacturer**	**510(k) #**	**Decision Date**
SOUNDSTAR eco 10F/10FG Ultrasound Catheter	Biosense Webster, Inc.	K112050	Nov 11, 2011
Reference Device Information			
AcuNav Crystal Ultrasound Catheter	Siemens Medical Solutions USA, Inc.	K233270	Oct 28, 2023

Table 2: Predicate and Reference Device Information

1.3 Description of the Device Subject to Premarket Notification [21 CFR 807.92(a) (4)]

The SOUNDSTAR CRYSTAL Ultrasound catheter is disposable and licensed for single use only. The catheter is optimized for intracardiac scanning. With the catheter, the physician can maneuver the imaging plane located inside the catheter tip to see the region of interest. The physician can steer the catheter to optimize tissue visualization. The catheter is to be used only on systems with which they have been tested and found compatible. The proposed device, when connected to the corresponding Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO® 3 EP Navigation System.

1.4 Intended Use [21 CFR 807.92(a) (5)]

Indications of Use: The SOUNDSTAR™ CRYSTAL Ultrasound Catheter and related accessory devices 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, the catheter provides location information. Refer to the 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.

1.5 Summary of Substantial Equivalence [21 CFR 807.92 (a) (6)]

Element of Comparison	Proposed/Subject Device	Predicate Device [K112050] [SoundStar *eco* 10F/10FG Ultrasound Catheter]	Reference Device [K233270] AcuNav Crystal Ultrasound Catheter
Device Name	SOUNDSTAR™ CRYSTAL Ultrasound Catheters	SoundStar *eco* 10F Ultrasound Catheter	AcuNav Crystal Ultrasound Catheter
510(k)	Subject Device	K112050	K233270
Manufacturer	Biosense Webster, Inc.	Biosense Webster, Inc.	Siemens Medical Solutions USA, Inc.
Indications for Use	The SOUNDSTAR™ CRYSTAL Ultrasound Catheter and related accessory devices 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, the catheter provides location information. Refer to the 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	The Biosense Webster SOUNDSTAR® eco Diagnostic Ultrasound Catheter and related accessory devices 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, the SOUNDSTAR® eco Catheter provides location information. Please refer to the Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO 3 and is not backwards	The 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.

	versions of the CARTO™ 3 EP Navigation System.	compatible with previous versions of CARTO® 3 EP Navigation Systems.	
Patient Population	Adult	Adult	Adult & Pediatric
Principle of Operations	Manual Control knobs on the handle provide bidirectional steering capabilities in 2 planes, left/right and posterior /anterior.	Manual Control knobs on the handle provide bidirectional steering capabilities in 2 planes, left/right and posterior /anterior.	Manual Control knobs on the handle provide bidirectional steering capabilities in 2 planes, left/right and posterior
Mode of Operation			
2D	X	X	X
M	X	X	X
C	X	X	X
D	X	X	X
MECHANICAL DESIGN CHARACTERISTICS			
Tip Dimensions	9F	10 F	9F
Insertable Length	90 cm	90 cm	90 cm
Function of handle	The handle houses the steering mechanism that enables deflection of the distal tip	The handle houses the steering mechanism that enables deflection of the distal tip	The handle houses the steering mechanism that enables deflection of the distal tip
OTHER DESIGN CHARACTERISTICS			
Radiopacity	Yes	Yes	Yes
Biocompatibility	Compliant to ISO 10993-1	Compliant to ISO 10993-1	Compliant to ISO 10993-1
Sterilization Method	EtO	EtO	EtO
Electrical Connector Plug	Twist and lock mechanism	Lever Mechanism	Twist and lock mechanism
Packaging configuration	Plastic tray, One Pouch, Non-Telescoping one-piece CCSBS unit	Paper board tray, Double Pouch, Telescoping two-piece CCSBS unit	Plastic tray, One Pouch, Non-Telescoping one-piece CCSBS unit

Table 3: Summary of Substantial Equivalence

Other changes include update in the acoustic array where the number and length of active element array are changed with respect to the predicate device. Also, the raw materials included addition of Mobilize Pebax Compounding Solutions from that of the predicate device. These changes have been verified by well-established protocols. Preclinical testing has been conducted to confirm that the acoustic array has equivalent acoustic property for imaging performance and Biocompatibility test under ISO 10993-1 has been conducted to confirm that there is no impact on the results from the change of catheter materials.

1.6 Performance Testing: [21 CFR 807.92(b)(1)]

The device has been evaluated for acoustic output, biocompatibility, sterilization, packaging, shelf life as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The device complies with the following voluntary standards:

- ISO 14971 risk management to medical devices
- ANSI/AAMI ES 60601-1 Safety Requirements for Medical Equipment
- IEC 60601-1-2 EMC requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- 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

1.6.1 Summary of Clinical Tests

The SOUNDSTAR™ CRSTAL Ultrasound catheter in this submission uses the same intended use, technology and principles as the predicate device and hence clinical data is not required to establish substantial equivalence.

1.7 Conclusion on Safety and Effectiveness [21 CFR 807.92(b) (3)]

The SOUNDSTAR™ CRYSTAL Ultrasound Catheter is substantially equivalent to its currently cleared predicate devices based on the successful completion of nonclinical bench testing and pre-clinical studies, as well as the technological comparison exhibiting similar principles of design, operation, and indications for use.