June 28, 2024

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

Re: K241540
Trade/Device Name: NUVISION™ Ultrasound Catheter; NUVISION™ NAV Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: May 30, 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.

510(k) Number *(if known)*
K241540

Device Name
NUVISION™ Ultrasound Catheter
NUVISION™ NAV Ultrasound Catheter

Indications for Use *(Describe)*
The NUVISION™ Ultrasound Catheter is indicated 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.

The NUVISION™ NAV 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 the compatible CARTO™ 3 EP Navigation System, the catheter provides location information. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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	NUVISION™ Ultrasound Catheter NUVISION™ NAV 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)	NuVision ICE Catheter [K201775] NUVISION™ NAV Ultrasound Catheter [K223766]

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

Predicate Device Information			
Predicate Device Name	**Manufacturer**	**510(k) #**	**Decision Date**
NuVision ICE Catheter	Biosense Webster, Inc	K201775	05 Mar 2021
NUVISION™ NAV Ultrasound Catheter	Biosense Webster, Inc	K223766	16 Feb 2023

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

The NUVISION™ Catheters are sterile, single use ultrasound catheters. They intended 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 of patients. The catheters are intended for imaging guidance only, not treatment or therapy delivery, during cardiac interventional percutaneous procedures.

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

Intended Use for NUVISION Ultrasound Catheter: The NUVISION™ Ultrasound Catheter is intended 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.

Indications for Use for NUVISION™ Ultrasound Catheter: The NUVISION™ Ultrasound Catheter is indicated 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.

Intended Use for NUVISION NAV Ultrasound Catheter: The NUVISION™ NAV Ultrasound Catheter is intended 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.

Indications for Use for NUVISION™ NAV Ultrasound Catheter: The NUVISION™ NAV 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 the compatible CARTO™ 3 EP Navigation System, the catheter provides location information. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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

NUVISION™ Ultrasound Catheter:

Element of Comparison	Proposed/Subject Device	Predicate Device [K201775]
Device Name	NUVISION™ Ultrasound Catheter	NuVision ICE Catheter
510(k)	Subject Device	K201775
Manufacturer	Biosense Webster, Inc.	Biosense Webster, Inc.
Regulation	21 CFR 870.1200	21 CFR 870.1200
Classification	Class II	Class II
Product code	OBJ	OBJ
Indications for Use	The NUVISION™ Ultrasound Catheter is indicated 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.	The NUVISION™ Ultrasound Catheter is indicated 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.

Patient Population	Adult and Pediatric	Adult and Pediatric
Outside Diameter	10F	10 F
Imaging Modes	B-Mode (2D and 3D) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D and 3D) Power Doppler	B-Mode (2D and 3D) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D and 3D) Power Doppler
Acoustic Array	Multi-element 2D phased array-on-ASIC ultrasound transducer at distal tip	Multi-element 2D phased array-on-ASIC ultrasound transducer at distal tip
Sterilization Method	EtO	EtO

NUVISION NAV Ultrasound Catheter:

Element of Comparison	**Proposed/Subject Device**	**Predicate Device [K223766]**
Device Name	NUVISION™ NAV Ultrasound Catheter	NUVISION™ NAV Ultrasound Catheter
510(k)	Subject Device	K223766
Manufacturer	Biosense Webster, Inc.	Biosense Webster, Inc.
Regulation	21 CFR 870.1200	21 CFR 870.1200
Classification	Class II	Class II
Product code	OBJ	OBJ
Indications for Use	The NUVISION™ NAV 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 the compatible CARTO™ 3 EP Navigation System, the catheter provides location information. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The NUVISION™ NAV Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the compatible CARTO™ 3 EP Navigation System, the catheter provides location information. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures
Patient Population	Adult	Adult
Outside Diameter	10.5 F	10 F
Imaging Modes	B-Mode (2D and 3D) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D and 3D) Power Doppler	B-Mode (2D and 3D) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D and 3D) Power Doppler
Acoustic Array	Multi-element 2D phased array-on-ASIC ultrasound transducer at distal tip	Multi-element 2D phased array-on-ASIC ultrasound transducer at distal tip
Sterilization Method	EtO	EtO

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

The NUVISION Ultrasound Catheter and NUVISION NAV Ultrasound Catheter are sterile, single-use, disposable intracardiac echo (ICE) ultrasound imaging catheters. The distal end of the catheter has an ultrasound transducer with 2D acoustic element array on ASIC enabling real time 2D, 3D, and multiplane imaging. NUVISION Ultrasound Catheter is compatible with GE Vivid™ S70N and GE E95 Ultrasound System to enable 4D intra-cardiac imaging. While the NUVISION NAV Ultrasound Catheter's grid transducer combines the processing power of the GE Vivid™ S70N Ultrasound System to enable 4D intra-cardiac imaging and when coupled with a 3D location sensor enables location mapping in a compatible CARTO 3 System. The transducer array can be rotated independently of the deflection plane of the catheter shaft. The NUVISION NAV Ultrasound Catheter adds integration into the CARTO environment. Both catheters met all acceptance criteria in accordance with appropriate test criteria and standards.

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

The NUVISION Ultrasound Catheter and NUVISION NAV Ultrasound Catheter are substantially equivalent to its currently cleared predicate devices based on the successful completion of nonclinical bench testing, as well as the technological comparison exhibiting similar principles of design, operation, and indications for use.