February 16, 2023

Biosense Webster, Inc.
Sheba Chacko
Senior Regulatory Affairs Program Lead
31 Technology Drive, Suite 200
Irvine, California 90618

Re: K223766
Trade/Device Name: NUVISION™ NAV Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: December 13, 2022
Received: December 15, 2022

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 (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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223766

Device Name
NUVISION™ NAV Ultrasound Catheter

Indications for Use *(Describe)*
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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Johnson & Johnson

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

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

Date Summary Prepared	15 February 2023
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™ 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
Classification Panel	Cardiovascular

Table 1:Submitter and Device Information

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

Predicate Device Information			
Predicate Device Name	**Manufacturer**	**510(k) #**	**Decision Date**
NUVISION ICE Catheter, 10F	NuVera Medical, Inc.	K201775	March 5, 2021
Reference Device Information			
SoundStar eco 10F Ultrasound Catheter	Biosense Webster, Inc.	K112050	Nov 11, 2011

Table 2: Predicate and Reference Device Information

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

The NUVISION™ NAV Ultrasound Catheter is a 10F sterile, single-use, disposable diagnostic ultrasound imaging catheter designed for intracardiac use. The distal tip of the catheter contains a 4D ICE ultrasound transducer, comprised of a 2D acoustic element array and ASIC, for real-time 2D, 3D, and multiplane intracardiac imaging. It is coupled with a sensor providing real-time 3D location information to the compatible CARTO™ 3 EP Navigation System with ultrasound capability. Knobs on the catheter handle allow the user to deflect the catheter and rotate the

transducer array independently of the deflection of the catheter shaft. The imaging field emanates from one side of the catheter tip, perpendicular to the axis of the catheter. The catheter may also be referred to as a probe in some instances.
The catheter is validated for use only with the GE Vivid™ S70N Ultrasound System (K223832), and the CARTO™ 3 EP Navigation System with CARTOSOUND™ 4D (K223733). The NUVISION™ Connector Cable is used to connect the catheter to the GE Ultrasound System and the multipin SOUNDSTAR™ eco Cable is used to connect the catheter to the CARTO™ 3 System.

4. Intended Use [21 CFR 807.92(a) (5)]

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.

4.1 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.

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

Description	NUVISION NAV Ultrasound Catheter (Subject Device)	NUVISION ICE Catheter (Predicate Device) K201775	SOUNDSTAR eco 10F/10FG Ultrasound Catheter (Reference Device) K112050
Classification	Class II	Class II	Class II
Regulation	21 CFR 870.1200	21 CFR 870.1200	21 CFR 870.1200
Product code	OBJ	OBJ	OBJ
Indications of 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	The NUVISION ICE 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.	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.

Description	NUVISION NAV Ultrasound Catheter (Subject Device)	NUVISION ICE Catheter (Predicate Device) K201775	SOUNDSTAR eco 10F/10FG Ultrasound Catheter (Reference Device) K112050
	percutaneous procedures.		
Patient Population	Adult	Adult and Pediatric	Adult
Single Use	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Outside Diameter	10F	10F	10F
Insertable length	90cm	90cm	90cm
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	Multi-element linear phased array ultrasound transducer at distal tip.
Ultrasound Imaging Frequency	4-10 MHz	4-10 MHz	4-10 MHz
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	B-Mode (2D only) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D only) Power Doppler
Biocompatibility	ISO 10993, Externally Communicating Device, Circulating Blood category	ISO 10993, Externally Communicating Device, Circulating Blood category	ISO 10993, Externally Communicating Device, Circulating Blood category

Table 3: Substantial Equivalence Table

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

6.1 Technical Characteristics:

The NUVISION NAV Ultrasound Catheter is a sterile, single-use, disposable intracardiac echo (ICE) ultrasound imaging catheter. It is built around the core design and technology of the existing NUVISION ICE Catheter (predicate device), 10 Fr. 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. 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. Additionally, it is also coupled with a 3D location sensor enabling location mapping in a compatible CARTO 3 System. The transducer array can be rotated independently of the deflection plane of the catheter shaft. The new catheter will integrate the handling, mechanical performance, and imaging capability of the NUVISION catheter and add integration into the CARTO environment.

6.2 Performance Data:

The NUVISION NAV Ultrasound Catheter underwent bench, animal, and biocompatibility testing to demonstrate substantial equivalence. Testing included mechanical integrity, deflection, device functionality, simulated use, biocompatibility, electrical properties, visualization, sterilization, packaging, shelf life, device maneuverability and signal quality, and animal testing to assess device effectiveness and safety. The catheter passed all intended criteria in accordance with appropriate test criteria and standards.

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

The NUVISION NAV Ultrasound Catheter is substantially equivalent to the currently marketed NUVISION ICE Catheter (K201775) and SOUNDSTAR eco 10F/10FG Ultrasound Catheter (K112050) 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.