July 10, 2023

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

Re: K231312
Trade/Device Name: PENTARAY® NAV ECO High Density Mapping Catheter, DECANAV® Mapping Catheter, Webster® CS Catheter with Auto ID, Webster® CS Catheter with EZ Steer Technology, Webster® CS Catheter with EZ Steer Technology with Auto ID
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: MTD, DRF
Dated: May 5, 2023
Received: May 5, 2023

Dear Caleb Lau:

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)*
K231312

Device Name
PENTARAY® NAV ECO High Density Mapping Catheter; DECANAV® Mapping Catheter; Webster® CS Catheter with Auto ID; Webster® CS Catheter with EZ Steer Technology; Webster® CS Catheter with EZ Steer Technology and Auto ID

Indications for Use *(Describe)*
PENTARAY® NAV ECO High Density Mapping Catheter:
The PENTARAY® NAV ECO High Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV ECO High Density Mapping Catheter provides location information when used with compatible CARTO®3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to version 3.x).

DECANAV® Mapping Catheter:
The DECANAV® Catheter is indicated for electrophysiological mapping of cardiac structures i.e., recording and stimulation, including in the coronary sinus. In addition, the catheter is used with compatible CARTO® 3 System to provide catheter tip location information.

Webster® CS Catheter with Auto ID, Webster® CS Catheter with EZ Steer Technology, Webster® CS Catheter with EZ Steer Technology and Auto ID:
The Webster® CS Catheter is indicated for electrophysiological mapping of cardiac structures i.e., stimulation and recording only. The catheter is designed for use in the 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.

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510(k) Summary

Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Caleb Lau Senior Regulatory Affairs Program Lead Phone: 949-704-1584 Fax: 949-450-6886
Date:	May 5, 2023
Device Trade Names:	PENTARAY® NAV eco High Density Mapping Catheter, DECANAV® Mapping Catheter, Webster® CS Catheter with Auto ID, Webster® CS Catheter with EZ Steer Technology Webster® CS Catheter with EZ Steer Technology and Auto ID
Device Common Name:	Electrophysiology Mapping Catheter
Model Numbers:	PENTARAY® NAV eco High Density Mapping Catheter: D-1282-07-S, D-1282-08-S, D-1282-09-S, D-1282-10-S, D-1282-11-S, D-1282-12-S DECANAV® Mapping Catheter: D-1285-01-S, D-1285-02-S Webster® CS Catheter with Auto ID D-1353-03-S, D-1353-04-S Webster® CS Catheter with EZ Steer Technology: D-1263-04-S, D-1263-05-S Webster® CS Catheter with EZ Steer Technology with Auto ID D-1263-06-S, D-1263-07-S
Device Classification:	Electrode Recording Catheter Class II, 21 CFR 870.1220

Product Codes	PENTARAY® NAV eco High Density Mapping Catheter: MTD DECANAV® Mapping Catheter: DRF Webster® CS Catheter with Auto ID: DRF Webster® CS Catheter with EZ Steer Technology: DRF Webster® CS Catheter with EZ Steer Technology with Auto ID: DRF
Predicate Devices:	PENTARAY® NAV eco High Density Mapping Catheter: PENTARAY® NAV eco High Density Mapping Catheter, cleared via 510(k) K201750 DECANAV® Mapping Catheter: DECANAV® Mapping Catheter, cleared via 510(k) K080425 Webster® CS Catheter with Auto ID: Webster® CS Catheter with Auto ID, incorporated via documentation (Letter to File) to K080425 Webster® CS Catheter with EZ Steer Technology: Webster® CS Catheter with EZ Steer Technology, cleared via 510(k) K101345 Webster® CS Catheter with EZ Steer Technology with Auto ID: Webster® CS Catheter with EZ Steer Technology with Auto ID, cleared via 510(k) K101345
Manufacturing Facilities:	Biosense Webster, Inc., Circuito Interior Norte 1820, Industrial Salvarcar, Ciudad Juarez, Chihuahua 32574, Mexico

Device Description:

PENTARAY® NAV eco High Density Mapping Catheter:

The PENTARAY® NAV eco High Density Mapping Catheter is a multi-electrode diagnostic catheter designed to facilitate electrophysiological mapping of all structures in the heart (recording and stimulation). The catheter's distal end is a flower-shaped probe with 5 spines that radiate from the center. Each spine has 4 ring electrodes that are used for stimulation and recording within the heart. The flower is available in a 30mm diameter and several ring spacing configurations to achieve optimal mapping and contact with various cardiac structures.

DECANAV® Mapping Catheter:

The DECANAV® Catheter has been designed to be used with the CARTO® 3 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 DECANAV® Catheter has a single proximal electrode that can be used for unipolar recording signals. The DECANAV® Catheter tip deflection is controlled by a proximal hand piece that features a thumb operated sliding piston and is offered in various curve types. The plane of the curved tip can be rotated during use.

The DECANAV® Catheter interfaces with standard recording equipment and CARTO® 3 EP Navigation System equipment via interface cables with the appropriate connectors.

Webster® CS Catheter with Auto ID:

The Webster® Coronary Sinus Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device is a 6 FR catheter with a usable length of 115 cm. The catheter has a high-torque shaft with a deflectable tip selection containing an array of platinum electrodes that can be used for stimulation and recording.

Standard features of this catheter include a braided 6 FR deflectable tip section with an array of platinum electrodes that includes a 2 mm tip dome. The braided tip is controlled by a proximal hand piece that features a thumb operated sliding piston, and is offered in a various curve types. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate position of the catheter tip at the desired site.

The catheter is equipped with Electronically Erasable Programmable Read Only Memory (EEPROM) which is used to store unique catheter identification information. CARTO® EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information.

The catheter interfaces with CARTO® EP Navigation Systems equipped with Auto ID Technology via interface cables with the appropriate connectors.

Webster® CS Catheter with EZ Steer Technology:

The Webster® CS Catheters with EZ Steer Bi-directional Technology (D-1263-04-S and D-1263-05-S) are diagnostic, 7F, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bi-directional deflection and are 115 cm long. These catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180˚ opposed single plane curves. Currently, the available curves include FJ (D-1263-04-S) and DF (D-1263-05-S). These catheters include a handle with a Rocker Lever, which is used to deflect the tip. 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 following cables are used to provide a means for interface of the catheters with the appropriate equipment:

- D-1221-21
- D-1221-26

- D-1221-25

Webster® CS Catheter with EZ Steer Technology and Auto ID:

The Webster CS Catheters with EZ Steer Bi-directional Technology (D-1263-06-S and D-1263-07-S) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bidirectional deflection and are 115 cm long. These catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180˚ opposed single plane curves. Currently, the available curves include FJ (D-1263-06-S) and DF (D-1263-07-S). These catheters include a handle with a Rocker Lever which is used to deflect the tip. 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 Webster CS Catheters with EZ Steer Bi-directional Technology and Auto ID (D-1263-06-S & D-1263-07-S) are equipped with Electronically Erasable Programable Read Only Memory (EEPROM) which is used to store unique catheter identification information.

CARTO 3 EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information. The catheters interface with CARTO 3 EP Navigation Systems via an interface cable (D-1286-16) with the appropriate connectors.

Indications for Use:

PENTARAY® NAV eco High Density Mapping Catheter

The PENTARAY® NAV eco High Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV eco High Density Mapping Catheter provides location information when used with compatible CARTO®3 EP

Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to version 3.x).

DECANAV® Mapping Catheter:

The DECANAV® Catheter is indicated for electrophysiological mapping of cardiac structures i.e., recording and stimulation, including in the coronary sinus. In addition, the catheter is used with compatible CARTO® 3 System to provide catheter tip location information.

Webster® CS Catheter with Auto ID, Webster® CS Catheter with EZ Steer Technology, Webster® CS Catheter with EZ Steer Technology and Auto ID:

The Webster® CS Catheter is indicated for electrophysiological mapping of cardiac structures i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

Technological Characteristics:

PENTARAY® NAV eco High Density Mapping Catheter:

The PENTARAY® NAV eco High Density Mapping Catheter is identical in design and all technological characteristics to the predicate PENTARAY® NAV eco High Density Mapping Catheter cleared under K201750. The main difference between the predicate device and the modified device is a change to the instructions for use to allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation.

DECANAV® Mapping Catheter:

The DECANAV® Catheter is identical in design and all technological characteristics to the predicate DECANAV® Catheter cleared under K080425. The main difference between the predicate device and the modified device is a change to the instructions for use to allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation.

Webster® CS Catheter with Auto ID:

The Webster® CS Catheter with Auto ID is identical in design and all technological characteristics to the

predicate Webster® CS Catheter with Auto ID incorporated by documentation (Letter to File) to K080425. The main difference between the predicate device and the modified device is a change to the instructions for use to allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation

Webster® CS Catheter with EZ Steer Technology (with and without Auto ID):

The Webster® CS Catheter is identical in design and all technological characteristics to the predicate Webster® CS Catheter cleared under K101345. The main difference between the predicate device and the modified device is a change to the instructions for use to allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation.

Performance Data: The subject devices underwent bench and animal testing and passed all intended criteria in accordance with appropriate test criteria and standards.

Clinical Data: A Real-World Evidence study (REAL AF Registry Sub-Study) evaluating the safety and acute effectiveness of Paroxysmal Atrial Fibrillation ablation with a zero/low fluoroscopy workflow was performed. The data from the study demonstrated the safety and effectiveness of zero/low fluoroscopy workflow. The primary safety and secondary acute effectiveness endpoints were met in the REAL AF Registry population. The safety of the zero/low fluoroscopy workflow was further corroborated by the comparable cumulative incidences of the secondary safety endpoint between the zero/low fluoroscopy group and the conventional fluoroscopy group.

Conclusions: The PENTARAY® NAV eco High Density Mapping Catheter, DECANAV® Mapping Catheter, Webster® CS Catheter with Auto ID, Webster® CS Catheter with EZ Steer Technology, and Webster® CS Catheter with EZ Steer Technology and Auto ID are substantially equivalent to their respective predicate devices based on the following: (1) clinical study data obtained from Real-World Evidence and (2) equivalence in terms of fundamental scientific technology based on the identical design, principles of operation, and indications for use.