August 6, 2020

Biosense Webster, Inc
Richard Lauhead
Sr. Program Lead, RA
33 Technology Dr
Irvine, California 92618

Re: K201750
Trade/Device Name: Pentaray Nav eco High-Density Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: June 19, 2020
Received: June 26, 2020

Dear Richard Lauhead:

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,

Mark Fellman
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

1. 510(K) SUMMARY

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

Date Summary Prepared	06 August 2020
Applicant	Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618 Establishment Registration Number: 9044811
Official Correspondent	Richard Lauhead Senior Program Lead, Regulatory Affairs Telephone: (949) 789-8583 Fax: (949) 450-6886
Trade Name	Pentaray Nav eco High Density Mapping Catheter.
Common Name	Electrophysiology Catheter
Classification Name	Electrode Recording Catheter
Device Classification	Class II, 21 CFR 870.1220 Product Code: MTD
Model Numbers	D-1282-07-S, D-1282-08-S, D-1282-09-S, D-1282-10-S, D-1282-11-S, D-1282-12-S
Predicate device	PENTARAY® Nav eco Mapping Catheter (K123837)

Substantially Equivalent To:

The Biosense Webster Inc. PENTARAY® Nav eco Mapping Catheter is substantially equivalent to the Biosense Webster Inc. PENTARAY® Nav eco Mapping Catheter [510(k) K123837 cleared March 05, 2013]. The subject catheter is identical in design to the current catheter. The intended use of the predicate device as a diagnostic catheter designed to facilitate mapping of structures within the heart remains the same in the subject device. The purpose of this 510(k) submission is to add clarification to the precautions. There are no other changes between the subject device and the predicate device approved per K123837.

Description of the Device Subject to Premarket Notification:

The Biosense Webster PENTARAY® Nav eco 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.

Indications for Use:

The Biosense Webster 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).

Technical Characteristics:

The PENTARAY™ NAV eco High-Density Mapping Catheter has a flower shaped tip containing 20 electrodes arranged across 5 spines Otherwise, there are no special technical aspects of the ability of this catheter to detect electrical signals from heart endocardium and transmit this information to the CARTO® 3 EP Navigation system and/or recording equipment for display, analysis, and interpretation in detection of various heart arrhythmias.

Performance Data:

The PENTARAY™ NAV eco High-Density Mapping Catheter underwent bench and animal testing. The catheter passed all intended criteria in accordance with appropriate test criteria and standards.

Basis for Determination of Substantial Equivalence:

The subject PENTARAY™ NAV eco High-Density Mapping Catheter is substantially equivalent to the predicate device, based on the identical principles of design, operation, and indications for use. The only change for the proposed device is the addition of an informative precaution