March 18, 2022

Biosense Webster, Inc.
John Jimenez
Senior RA Program Lead
31 Technology Drive Suite 200
Irvine, California 92618

Re: K211438
Trade/Device Name: OPTRELL™ Mapping Catheter with TRUEref™ Technology
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: February 16, 2022
Received: February 18, 2022

Dear John Jimenez:

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 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)*
K211438

Device Name
OPTRELL™ Mapping Catheter with TRUEref™ Technology

Indications for Use *(Describe)*
The OPTRELL™ Mapping Catheter with TRUEref™ Technology 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 catheter provides location information only when used with a compatible version of the CARTO™ 3 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	4 August 2021
510(k) Number	K211438
Applicant	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618 Establishment Registration Number: 9044811
Official Correspondent	John Jimenez Senior Program Lead, Regulatory Affairs Telephone: (949) 923-4774 Fax: (949) 450-6886
Trade Name	OPTRELL™ Mapping Catheter with TRUEref™ Technology
Common Name	Electrophysiology Catheter
Classification Name	Cardiovascular Catheter
Device Classification	Class II, 21 CFR 870.1220 Product Code: DRF
Part Numbers	D-1409-01-S, D-1409-02-S
Predicate device	CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology (K193237)

Substantially Equivalent To:

The Biosense Webster Inc. OPTRELL™ Mapping Catheter with TRUEref™ Technology is substantially equivalent to the Biosense Webster Inc. CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology [510(k) K193237 cleared July 31, 2020]. Like the predicate device, the OPTRELL™ Mapping Catheter with TRUEref™ Technology is an 8 French (Fr) diagnostic catheter incorporating the same forty-eight (48) electrode design. They are only formatted in a paddle versus flower shaped array. It also incorporates a

TRUEref™ electrode at the distal tip of the irrigation lumen for use as an internal close unipolar reference electrode within the heart chamber. Lastly, the proposed catheter is offered in the same deflectable curve offerings as the predicate, with one additional offering. The deflection mechanism is bi-directional versus uni-directional, allowing two curve offerings in the same catheter. The original intended use of the predicate device as a diagnostic catheter designed to facilitate mapping of structures within the heart remains the same in the proposed device.

Description of the Device Subject to Premarket Notification:

The OPTRELL™ Mapping Catheter with TRUEref™ Technology is designed to facilitate electrophysiological mapping of the heart with the CARTO™ 3 System. It is designed for deployment in a heart chamber through an 8.5 Fr guiding sheath. This bi-directional deflectable catheter includes six (6) parallel 2 Fr spines that are joined to form three (3) loops on the deflectable tip. Each spine has eight (8) platinum electrodes that are used for stimulating and recording. The electrodes form a 6 by 8 (6x8) grid. A magnetic location sensor embedded in the deflectable tip transmits location information to the CARTO™ 3 EP Navigation System. Below the spines on the deflectable tip are three (3) electrodes that allow visualization of the tip on the CARTO™ 3 System. The TRUEref™ Electrode, which is embedded in the distal end of the irrigation lumen, can be used as an internal close unipolar reference electrode within the heart chamber. Rotating the catheter's Rocker Lever clockwise or counterclockwise deflects the tip; rotating the Rocker Lever to the neutral position straightens the tip. The catheter includes an irrigation lumen for connection to a source of continuous drip anticoagulant fluid.

Indications for Use:

The OPTRELL™ Mapping Catheter with TRUEref™ Technology 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 catheter provides location information only when used with a compatible version of the CARTO™ 3 System.

Technical Characteristics:

The OPTRELL™ Mapping Catheter with TRUEref™ Technology design uses similar technology, has similar intended use, functions, materials and method of operation as the predicate CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology. Instead of an eight (8) flower shaped tip, the OPTRELL™ Mapping Catheter with TRUEref™ Technology has a paddle-shaped tip containing forty-eight (48) electrodes arranged across six (6) spines. Like the predicate, OPTRELL™ also includes a close uni-polar reference electrode located at the confluence of the 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. The difference in tip shape between the OPTRELL™ Mapping

Catheter with TRUEref™ Technology and the CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology have been evaluated through bench, animal, and biocompatibility testing. Results from the bench, animal, and biocompatibility data demonstrated that the proposed device is substantially equivalent to the predicate device and did not result in new questions with regards to safety and effectiveness of the device.

Performance Data:

The OPTRELL™ Mapping Catheter with TRUEref™ Technology 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.

Basis for Determination of Substantial Equivalence:

The OPTRELL™ Mapping Catheter with TRUEref™ Technology is substantially equivalent to its currently cleared predicate, CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology, 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.