March 2, 2023

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

Re: K230253
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: January 27, 2023
Received: January 31, 2023

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 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)*
K230253

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.

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2. 510(K) SUMMARY

Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618 Phone: (949) 923-4774 Fax: 949-450-6886
Contact Person:	John Jimenez Senior Program Lead, Regulatory Affairs
Date:	January 27, 2023
Trade or Proprietary Name:	OPTRELL™ Mapping Catheter with TRUEref™ Technology
Common or Usual Name of Device:	Electrophysiological Mapping Catheter
Classification Name:	Electrode Recording Catheter (21 CFR 870.1220, Product Code MTD)
Predicate Device:	OPTRELL™ Mapping Catheter with TRUEref™ Technology 510(k): K211438
Manufacturer:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618
Manufacturing Sites:	Biosense Webster, Inc. Circuito Interior Norte #1820 Parque Industrial Salvarcar 32599 Juarez, Chihuahua, Mexico

A. Substantially Equivalent To

The OPTRELL™ Mapping Catheter with TRUEref™ Technology is substantially equivalent to the Biosense Webster OPTRELL™ Mapping Catheter with TRUEref™ Technology cleared on March 18, 2022, under 510(k) K211438.

B. Description of the Device Subject to Premarket Notification

The OPTRELL™ Mapping Catheter with TRUEref™ Technology has been designed to facilitate electrophysiological mapping of the heart with the CARTO™ 3 System. The OPTRELL™ Mapping Catheter with TRUEref™ Technology is deployed in the heart through an 8.5 F 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 six (6) platinum electrodes that are used for stimulating and recording. The electrodes form a 6 by 6 (6x6) 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. Lastly, the proposed catheter is offered in the same deflectable curve offerings as the predicate.

The OPTRELL™ Mapping Catheter with TRUEref™ Technology design uses the same technology, has the same intended use, functions, materials, and method of operation as the predicate OPTRELL™ Mapping Catheter with TRUEref™ Technology. Instead of eight (8) platinum electrodes on each spine, the proposed OPTRELL™ Mapping Catheter with TRUEref™ Technology has six (6) electrodes on each spine, forming a 6 by 6 paddle-shaped tip containing thirty-six (36) electrodes arranged across six (6) spines. Like the predicate, the proposed 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 paddle size and number of electrodes between the proposed OPTRELL™ Mapping Catheter with TRUEref™ Technology and the predicate OPTRELL™ Mapping Catheter with TRUEref™ Technology have been evaluated through bench and animal testing. Results from the bench and animal 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.

C. 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.

D. Performance Data

The OPTRELL™ Mapping Catheter with TRUEref™ Technology underwent Bench and Animal Testing. Testing included mechanical integrity, deflection, device functionality, simulated use, electrical properties, visualization, 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. No new questions of safety or effectiveness were identified. Testing demonstrated that the proposed OPTRELL™ Mapping Catheter with TRUEref™ Technology is as safe, effective, and performs as well as or better, than the predicate device. This testing program supports the determination of substantial equivalence to the predicate device.

E. Overall Performance Conclusions

The nonclinical studies demonstrate that the OPTRELL™ Mapping Catheter with TRUEref™ Technology is as safe, effective, and performs as well as or better, than the predicate OPTRELL™ Mapping Catheter with TRUEref™ Technology.