July 31, 2020

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

Re: K193237
Trade/Device Name: Carto Octaray 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: June 29, 2020
Received: July 1, 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 Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193237

Device Name

CARTO® OCTARAY™ MAPPING CATHETER WITH TRUEREF™ TECHNOLOGY

Indications for Use *(Describe)*

The CARTO® OCTARAY™ 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 compatible versions of the CARTO® 3 EP Navigation 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.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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	25 June 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	CARTO® OCTARAY™ MAPPING CATHETER WITH TRUEREF™ TECHNOLOGY
Common Name	Electrophysiology Catheter
Classification Name	Electrode recording Catheter
Device Classification	Class II, 21 CFR 870.1220 Product Code: MTD
Model Numbers	D-1609-01-S, D-1609-02-S, D-1609-03-S, D-1609-04-S, D-1609-05-S, D-1609-06-S
Predicate device	PENTARAY® Nav eco Mapping Catheter (K123837)

Substantially Equivalent To:

The Biosense Webster Inc. CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology is substantially equivalent to the Biosense Webster Inc. PENTARAY® Nav eco Mapping Catheter [510(k) K123837 cleared March 05, 2013]. Like the predicate device, the CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology features a piston like deflection mechanism, allowing for uni-directional deflection of the shaft. The proposed catheter also has similar deflectable curve offerings and a similar flower shaped distal tip. 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 Biosense Webster CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology 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 8 spines that radiate from the center. Each spine has 6 ring electrodes that are used for stimulation and recording within the heart. The catheter also includes an electrode located at the confluence of the spines that can be used as a close internal unipolar reference. The flower is available in a 30mm or a 40 mm diameter and several ring spacing configurations to achieve optimal mapping and contact with various cardiac structures.

Indications for Use:

The CARTO® OCTARAY™ 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 compatible versions of the CARTO® 3 EP Navigation System.

Technical Characteristics:

The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ design uses similar technology, has similar intended use, functions, materials and method of operation as the predicate PENTARAY® Nav eco Mapping Catheter. The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology has a flower shaped tip containing 48 electrodes arranged across 8 spines and includes a close uni-polar reference electrode 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 differences in the number of spines and electrodes between the CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology and the PENTARAY® Nav eco Mapping Catheter have been evaluated through bench, animal and biocompatibility testing. Bench, clinical and animal testing demonstrated that the subject device is substantially equivalent to the predicate device. Results from the bench, animal, biocompatibility, and clinical data did not result in new questions with regards to safety and effectiveness of the device.

Performance Data:

The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology underwent bench testing, animal testing, and Clinical testing to demonstrate substantial equivalence.

Testing included Mechanical integrity, electrical leakage, deflection, device functionality, simulated use, biocompatibility, electrical properties, visualization and navigation, sterilization, packaging, shelf life, Animal testing to assess device safety, device maneuverability and signal quality, and clinical testing to assess device effectiveness and safety.

The catheter passed all predetermined acceptance criteria.

The Clinical study was a prospective, single arm, non-randomized, multi-center study. The study intended to enroll 30 subjects with a target of equal numbers of subjects (n=10) among three study arrhythmia subgroups: ischemic ventricular tachycardia, scar related AT (including PAF re-do/repeat procedures), and PsAF. The Study was performed outside of the United States.

The Primary objectives include meeting an effectiveness endpoint of completing pre-ablation mapping and clinically indicated mapping without the need for another device and a safety endpoint of having no serious adverse events within 7 days of the study procedure.

The study population included subjects scheduled to have a clinically-indicated catheter mapping and ablation procedure for management of an arrhythmia in the following 3 subgroups: Ischemic ventricular tachycardia (VT) n=31, Scar-related atrial tachycardia (AT; includes atypical atrial flutter) resulting from previous paroxysmal atrial fibrillation (PAF) ablation procedures, mitral valve repair procedures, or PAF "re-do" procedures n=30, and Persistent Atrial Fibrillation (PsAF) n=30.
Table A summarizes the Subject enrollment.
Table B summarizes subject demographic information

Table A - Subject Enrollment and Accountability (Enrolled Subjects, N=31)

Disposition	All Enrolled (N=31) n (%)	VT (n=11) n (%)	AT/PAF (n=10) n (%)	PsAF (n=10) n (%)
Enrolled Subjects	31 (100.0%)	11 (100.0%)	10 (100.0%)	10 (100.0%)
No study catheter inserted	1 (3.2%)*	0 (0.0%)	0 (0.0%)	1 (10.0%)*
Safety Population	30 (96.8%)	11 (100.0%)	10 (100.0%)	9 (90.0%)
Catheter inserted but no mapping	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mapping performed but not for study arrhythmia	2 (6.5%)†	1 (9.1%)†	0 (0.0%)	1 (10.0%)†
Per Protocol Population	28 (90.3%)	10 (90.9%)	10 (100.0%)	8 (80.0%)

* Subject 632-003 did not meet eligibility criteria and was withdrawn prior to a study procedure
† Subjects 847-001 (PsAF) & 847-003 (VT) had mapping performed despite not having study arrhythmia

Table B – Study Demographic information (Enrolled Subjects, N=31)

Disposition	All Arrhythmias (n=31)	OCTARAY FIM AT/PAF (n=10)	OCTARAY FIM PsAF (n=10)	OCTARAY FIM VT (n=11)
Age at Consent				
Mean ± SD (n)	67.8 ± 8.52 (31)	64.5 ± 9.23 (10)	68.1 ± 7.75 (10)	70.5 ± 8.25 (11)
Median (Q1/Q3)	66.0 (63.0,74.0)	65.5 (57.0,73.0)	68.0 (63.0,72.0)	69.0 (64.0,79.0)
Min / Max	51.0 / 83.0	51.0 / 76.0	54.0 / 79.0	57.0 / 83.0
Sex, n/N (%)				
Male	27 (87.1%)	9 (90.0%)	7 (70.0%)	11 (100.0%)
Female*	4 (12.9%)	1 (10.0%)	3 (30.0%)	0 (0.0%)
Race, n/N (%)				
Black/African American	1 (3.2%)	0 (0.0%)	1 (10.0%)	0 (0.0%)
White	25 (80.6%)	8 (80.0%)	9 (90.0%)	8 (72.7%)
Race not reported	5(16.1%)	2(20.0%)	0(0.0%)	3(27.3%)
Ethnicity, n/N (%)				
Not Hispanic or Latino	9 (90.0%)	9 (90.0%)	10 (100.0%)	7 (63.6%)
Not Reported	5(16.1%)	1(10.0%)	0(0.0%)	4(36.4%)

Study Results:

The study met Primary endpoints for both safety and effectiveness.
No Serious Adverse events were reported resulting from the use of the study catheter and all physicians were able to perform pre-ablation mapping with the subject device.

In the Per-Protocol Population, 82.1% (23/28) had pre-ablation mapping requirements successfully performed without the need of another catheter.

- Three (3) VT subjects did not have LAT mapping performed for reasons of patient safety. It is the position of the Sponsor that these were acceptable minor protocol deviations for patient safety and that the associated endpoint failures do not reflect a

deficiency of the catheter's ability to map but rather a unique unforeseen scenario. Pre-ablation voltage mapping was successfully performed for these subjects.
- One (1) VT subject did not have LAT mapping completed due to the operator's inability to maintain stable contact with the area of interest; the Sponsor has made note of this operator's feedback.
- One (1) PsAF subject that had CARTOFINDER mapping performed out of sequence was due to human error and was not affected by the catheter design or protocol prescribed workflow.

Clinically indicated mapping was started and finished in 100.0% (15/15) without the need for another device.

The study had 17 adverse events occur across 12 subjects and all were classified as unrelated to the study device. The Adverse Events reported include: Heart Failure, thoracic pain, perifissural nodule, Flu, constipation (two separate subjects), bladder infection, fever, hematuria, AV block 2:1, Dizziness, shoulder bruises, sore throat, non cardiac chest aches, shortness of breath, headaches, and allergic reaction.

Basis for Determination of Substantial Equivalence:

The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology is substantially equivalent to its currently cleared predicate, PENTARAY Nav eco Mapping Catheter, based on the successful completion of nonclinical bench testing, pre-clinical animal studies, a clinical study, as well as the technological comparison exhibiting similar principles of design, operation, and indications for use.