January 26, 2022

Biosense Webster, Inc.
Michelle Wheeler
Senior Regulatory Affairs Specialist
31 Technology Drive Suite 200
Irvine, California 92618

Re: K211219
Trade/Device Name: LASSOSTAR™ NAV Circular Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: April 22, 2021
Received: April 23, 2021

Dear Michelle Wheeler:

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)*
K211219

Device Name
LASSOSTAR™ NAV Circular Mapping Catheter

Indications for Use *(Describe)*
The LASSOSTAR™ NAV Circular Mapping Catheter is indicated for multiple electrode electrophysiology recording and stimulation of the atrial region of the heart. The catheter can be used with a compatible CARTO™ 3 System to provide location information and to create three-dimensional electroanatomic maps. (The catheter is not compatible with CARTO™ 3 Systems prior to Version 7.)

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

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

Date Summary Prepared	September 22, 2021
Applicant	Biosense Webster, Inc. 31 Technology Drive Suite 200 Irvine, CA 92618 Establishment Registration Number: 9044811
Official Correspondent	Michelle Wheeler Senior Regulatory Affairs Specialist Telephone: (949) 923-4793 Fax: (949) 450- 6886
Trade Name	LASSOSTAR™ NAV Circular Mapping Catheter
Common Name	Electrophysiology Catheter
Classification Name	Catheter, Electrode Recording, Or Probe, Electrode Recording
Device Classification	Class II, 21 CFR 870.1220 Product Code: DRF
Device Configuration	D-1404-01-S, D-1404-02-S, D-1404-03-S
Predicate device	LassoStar™ (K193632)

Substantially Equivalent
The Biosense Webster Inc. LASSOSTAR™ NAV Circular Mapping Catheter is substantially equivalent to the Biosense Webster Inc. LassoStar™ Non Nav Circular Mapping Catheter [510(k) K193632 cleared June 30, 2020].

Description of the Device Subject to Premarket Notification
The Biosense Webster LASSOSTAR™ NAV Circular Mapping Catheter is a 3.5 Fr, multi-electrode electrophysiological circular mapping catheter designed to provide location information and to create three-dimensional electroanatomic maps of the heart. On its distal tip, the catheter has a loop with platinum electrodes that can be used for recording and stimulation. The tip has an embedded sensor that allows the catheter to provide location information and create three-dimensional electroanatomic maps when used with a compatible Biosense Webster Inc. CARTO™ 3 System. The catheter is available in three loop diameters: 15 mm, 20 mm and 25 mm to allow for use in pulmonary veins of differing size. The catheter can be visualized using

conventional systems (such as fluoroscopy or ultrasound imaging), or with a compatible CARTO™ 3 System via interface cables with the appropriate connectors. The LASSOSTAR™ NAV Circular Mapping catheter has three product configurations (D-1404-01-S, D-1404-02-S, D-1404-03-S).

Indications for Use

The LASSOSTAR™ NAV Circular Mapping Catheter is indicated for multiple electrode electrophysiology recording and stimulation of the atrial region of the heart. The catheter can be used with a compatible CARTO™ 3 System to provide location information and to create three-dimensional electroanatomic maps. (The catheter is not compatible with CARTO™ 3 Systems prior to Version 7.)

Technological Characteristics

The LASSOSTAR™ NAV Circular Mapping Catheter uses similar technology and method of operation as the predicate device. The subject device includes the same number of electrodes, loop diameters, distal end shape and spine cover material as the predicate. The main differences of the subject device are the usable length, Carto™ compatibility, french size, shaft material and navigation sensor feature. **Table 2-1** provides a summary comparison of the Technological features of the subject and predicate device.

Table 2-1: Characteristic Comparison

Subject Area	**Subject Device (LASSOSTAR NAV)**	**Predicate Device (LASSOSTAR Non Nav, K193632)**
Product Code	DRF	DRF
Indications for Use	The LASSOSTAR™ NAV Circular Mapping Catheter is indicated for multiple electrode electrophysiology recording and stimulation of the atrial region of the heart. The catheter can be used with a compatible CARTO™ 3 System to provide location information and to create three-dimensional electroanatomic maps. (The catheter is not compatible with CARTO™ 3 Systems prior to Version 7.)	The LassoStar™ Circular Mapping Catheter is indicated for multiple electrode electrophysiological recording and stimulation of the atrial region of the heart. The catheter is designed to obtain electrograms in the atrial region of the heart.
Outer Diameter	3.5 French	3 French
Usable catheter Length	179 cm $\pm$ 1.0cm	193 cm $\pm$ 3.0cm
Number of Electrodes	10	10
Distal End Shape	Circular loop	Circular loop
Loop Diameter	3 sizes: 15mm, 20mm, 25mm	3 sizes: 15mm, 20mm, 25mm
Spine Cover Material	Pellethane	Pellethane
Shaft Material	Stainless Steel with Polyimide jacket	Stainless Steel

Method of Tip Deflection	No deflection	No deflection
CARTO compatibility	Carto 3, Version 7 and higher	Carto 3 visualization following mapping with navigational catheter
Navigation Sensor	Yes	No

Performance Data

The LASSOSTAR™ NAV circular catheter underwent bench and animal testing using similar pre-determined acceptance criteria as the predicate device. Testing was completed to support the subject modifications. The GLP animal study evaluated various sizes of deflectable sheaths and a catheter with a guide wire lumen to determine mapping capabilities of the subject device. The decreased outer diameter and change in shaft material were analyzed using functional and biocompatibility testing. The results of the testing demonstrate the device in scope of this premarket notification meet the product requirements with appropriate test criteria and standards. The following tests were performed in support of the substantial equivalence determination:

- Visual Inspections
- Electrical
- EEPROM Burn Checks
- Buckle Force
- Insertion
- Torque
- Tensile Strength
- Impedance and resistance
- Visualization
- Packaging Sterile Barrier Gross Leak
- Transportation
- Sterilization
- Simulated Use
- Electrical Compatibility

Conclusion

The LASSOSTAR™ NAV Circular Mapping Catheter is substantially equivalent to the currently cleared predicate device and is considered as safe and as effective as the predicate device.