June 30, 2020

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

Re: K193632
Trade/Device Name: LassoStar 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: May 19, 2020
Received: May 21, 2020

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193632

Device Name
LassoStar™ Circular Mapping Catheter

Indications for Use *(Describe)*
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.

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 21 CFR 807.92

Date Summary Prepared	23 December 2019
Applicant	Biosense Webster, Inc. 33 Technology Drive 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™ Circular Mapping Catheter
Common Name	Electrophysiology Catheter
Classification Name	Electrode Recording Catheter or Electrode Recording Probe
Device Classification	Class II, 21 CFR 870.1220 Product Code: DRF
Model Numbers	D-1390-01-S, D-1390-02-S, D-1390-03-S
Predicate device	Lasso™ Deflectable Circular Mapping Catheter (K002333)

Substantially Equivalent
The Biosense Webster Inc. LassoStar™ Catheter is substantially equivalent to the Biosense Webster LASSO™ Deflectable Circular Mapping Catheter [510(k) K002333 cleared August 31, 2000].

Description of the Device Subject to Premarket Notification
The Biosense Webster LassoStar™ Circular Mapping Catheter is a multi-electrode circular diagnostic catheter designed to facilitate electrophysiological mapping of the atria of the heart (recording and stimulation). The catheter's distal end is a circular spine with ten ring electrodes located circularly that are used for stimulation and recording within the atria. The loop is available in multiple diameters (15 mm, 20 mm and 25 mm) to achieve optimal contact in variably sized pulmonary veins. The device is provided sterile (EtO) and intended for single use.

Indications for Use

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.

Technological Characteristics

The LassoStar™ Circular Mapping Catheter uses similar technology, intended use and method of operation as the predicate device. The proposed device includes the same number of electrodes, loop diameters, distal end shape and spine cover material as the predicate device. The main differences of the proposed device are the outer diameter size, shaft material and method of tip deflection mechanism. **Table 2-1** provides a direct comparison of the Technological features of the proposed and predicate device.

Table 2-1: Characteristic Comparison

Subject Area	**Proposed Device (LASSOSTAR)**	**Predicate Device (Lasso, K002333)**
Product Code	DRF	DRF
Indications for Use	The Biosense Webster 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	The catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures, i.e. recording or stimulation only. The Lasso Catheter is designed to obtain electrograms in the atrial region of the heart.
Outer Diameter	3 French	7 French
Usable catheter Length	193 cm ± 3.0cm	115 cm ± 5.0cm
Number of Electrodes	10	10 or 20
Distal End Shape	Circular loop	Circular loop
Loop Diameter	3 sizes: 15mm 20mm 25mm	6 sizes: 12mm 25mm 15mm 30mm 20mm 35mm
Spine Cover Material	Pellethane	Pellethane
Shaft Material	Stainless Steel	Pebax
Method of Tip Deflection	No deflection	deflection

Performance Data

The LassoStar™ catheter underwent bench and animal testing using similar pre-determined acceptance criteria as the predicate device. Testing was completed to support the proposed modifications. The GLP animal study evaluated various sizes of deflectable sheaths to determine mapping capabilities of the proposed device with no deflection. 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. 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
- Biocompatibility
- Sterilization
- Simulated Use

Basis for Determination of Substantial Equivalence

The LassoStar™ Circular Mapping Catheter is substantially equivalent to the currently cleared predicate device. The performance data supports the safety and effectiveness of the proposed device and demonstrates the device should perform as intended in the specified use conditions.