July 10, 2023

Biosense Webster, Inc.
Caleb Lau
Senior Regulatory Affairs Program Lead
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K231412
Trade/Device Name: CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath (D-1385-01-S, D-1385-02-S, D-1385-03-S)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 16, 2023
Received: May 16, 2023

Dear Caleb Lau:

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.

Submission Number *(if known)*

K231412

Device Name

CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath (D-1385-01-S, D-1385-02-S, D-1385-03-S)

Indications for Use *(Describe)*

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with compatible CARTO® EP Navigation Systems.

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

Prepared on: 2023-05-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biosense Webster, Inc.
Applicant Address	31 Technology Drive, Suite 200 Irvine CA 92618 United States
Applicant Contact Telephone	949-704-1584
Applicant Contact	Mr. Caleb Lau
Applicant Contact Email	clau21@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath (D-1385-01-S, D-1385-02-S, D-1385-03-S)
Common Name	Catheter introducer
Classification Name	Introducer, Catheter
Regulation Number	870.1340
Product Code	DYB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170997	CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath	DYB

Device Description Summary

21 CFR 807.92(a)(4)

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is designed to provide accessibility and maneuverability in the cardiac anatomy. The steerable sheath is fitted with a hemostatis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, and fluid infusion. A handle equipped with a rotating collar to deflect the tip clockwise ≥ 180º and counterclockwise ≥ 180º. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to allow fluoroscopic visualization. The steerable sheath is coated with silicone lubricant on the entire shaft and dilator surface to help minimize friction at the insertion site.

The sheath has electrodes on the outer surface to allow interface with compatible CARTO® 3 EP Navigation Systems.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with compatible CARTO® EP Navigation Systems.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The predicate device is the CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath, 510(k)#: K170997.

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is substantially equivalent to the legally marketed device, as defined in FDA's The 510(k) Program: Evaluating Substantial Equivalence in the Premarket Notifications [510(k)]. The sole purpose of this submission is to revise the instructions for use (IFU) to (1) allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation, and (2) to adhere to FDA Guidance "Intravascular Catheters, Wire, and Delivery Systems with Lubricious Coatings - Labeling Considerations" (October 2019).

Intended Use: The proposed CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath has the same intended use as the predicate CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath. Specifically, both devices are indicated for introducing various cardiovascular catheters into the heart, including the left of the heart through the interatrial septum.

Technological Comparison

21 CFR 807.92(a)(6)

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is identical in technological characteristics with the predicate device, as there are no changes in the materials, design, or other features of the device from those of the CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath cleared under K170997.

The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is a typical bi-directional guiding sheath that is unique only in the presence of four ring electrodes spaced along its shaft. Otherwise, there are no special technical aspects of the ability of this sheath to facilitate the introduction of various cardiovascular catheters into the heart.

The safety and performance of the CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath with the additional workflow has been validated through clinical study data. Since the catheter design and intended use is identical for the proposed device and predicate device, there is no significant difference in the safety and performance of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The clinical study data demonstrated that the CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is as safe and effective as the predicate device. The CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath is substantially equivalent to the predicate device in terms of fundamental scientific technology based on the identical design, principles of operation, and indications for use.