DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 25, 2017

Biosense Webster, Inc.
John Jimenez
Senior Program Lead, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K170997
Trade/Device Name: CARTO VIZIGO 8.5F Bi-Directional Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 9, 2017
Received: June 12, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170997

Device Name
CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath

Indications for Use *(Describe)*
The Biosense Webster 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® 3 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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1. 510(K) SUMMARY

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

APPLICANT	Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618
OFFICIAL CORRESPONDENT	John Jimenez Senior Program Lead, Regulatory Affairs Telephone: 949-923-4774 Fax: 949-450-6886 Email: jjimene7@its.jnj.com
DATE SUMMARY PREPARED	March 31, 2017
TRADE NAME	CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath
COMMON NAME	Guiding Sheath
CLASSIFICATION NAME	Catheter Introducer
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1340 Product Code: DYB
PRODUCT CODES	D-1385-01-S, D-1385-02-S, D-1385-03-S
PREDICATE DEVICE	St. Jude Agilis™ NxT Steerable Introducer [510(k) K081645]
REFERENCE DEVICE	Webster® CS Catheter with EZ Steer® Technology [510(k) K101345]

SUBSTANTIALLY EQUIVALENT TO:

The Biosense Webster CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is substantially equivalent to the St. Jude Agilis™ NxT Steerable Introducer [510(k) K081645, cleared December 9, 2008]. Like the predicate device, the CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath features a rotary-type deflection mechanism, allowing for bi-directional deflection of the shaft. The proposed sheath also has similar Flex Shaft Curve Size offerings, the same French Size, the same patient contact materials, and the same Useable Length. The original intended use of the predicate device as a catheter delivery system remains the same in the proposed device; however, the proposed device will now have the added ability of shaft visualization when used with a compatible

CARTO® 3 EP navigation System. This latter capability is substantially equivalent to and can be referenced in the Webster® CS Catheter with EZ Steer® Technology. The Webster® CS Catheter with EZ Steer® Technology utilizes the same visualization technology and was approved under 510(k) K101345, cleared June 22, 2010.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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 hemostasis 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 ≤ 180° and counterclockwise ≤ 180°. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to allow fluoroscopic visualization. The purpose of this Premarket Notification is to create a bi-directional, flexible-tipped, guiding sheath, with visualization capabilities to facilitate catheter accessibility to various areas of interest within the heart. The new sheath will utilize an existing cable/connector to support visualization.

The CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath features a flex shaft curve design available in three curve sizes, Small, Medium, and Large curve. Each sheath with four (4) electrodes spaced along its shaft to enable shaft visualization when used with compatible CARTO® 3 EP Navigation Systems.

INDICATIONS FOR USE:

The Biosense Webster 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® 3 EP Navigation Systems.

TECHNICAL CHARACTERISTICS:

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.

PERFORMANCE DATA:

The CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath underwent bench and pre-clinical testing under simulated clinical conditions to verify the safety and effectiveness of its features. The CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath passed all tests in accordance with appropriate test criteria and standards.

Summary of Bench Tests and Results

Test Description	Results
Usable Length	Pass
Lumen Inner Diameter	Pass
Distal Tip Inner Diameter	Pass
Overall Length	Pass
Cap to hub retention	Pass
Sheath OD	Pass
Sheath OD – Flex Section	Pass
PU adhesion	Pass
Marker Band Location[1]	Pass
Vent Hole Location	Pass
Vent Hole Diameter	Pass
Vent Hole Orientation	Pass
Sheath leak	Pass
Vacuum decay	Pass
In-Plane Deflection	Pass
Handle deflection direction	Pass
Shaft torque	Pass
Tip drag force	Small: Pass
	Large: Pass
Side load	Small: Pass
	Large: Pass
Pigtail to Connector[2]	Pass
Pigtail to Handle	Pass
Hub to shaft	Pass
Stopcock to handle	Pass
Stopcock to tube	Pass
Shaft distal segments	Pass
Shaft proximal segments	Pass
Hemostasis valve and sheath must not leak	Pass
Valve insertion force	Pass
Valve friction	Pass
Curve Span	Small: Pass
	Large: Pass
Electrode Location	Small: Pass
	Large: Pass
Electrical Resistance	Small: Pass
	Large: Pass
Current Leakage	Small: Pass
	Large: Pass
Connector mating, flex fatigue, and pigtail torque testing	Pass
Electrical Isolation	Small: Pass
	Large: Pass
External lead cable length	Pass
Corrosion	Pass
Continuous pouch seal	Pass
Pouch particulate	Pass
Label adhesion and legibility	Pass
Dilator OD	Pass
Dilator to cap retention force	Pass
Dilator to dilator hub tensile	Pass
Dilator hub has standard luer	Pass
Dilator overall length (straightened)	Pass
Dilator tip ID	Pass

Summary of Pre-Clinical Tests and Results

The study placed one Test or one Control sheath in the animal to aid in maneuvering of various therapeutic and diagnostic catheters for mapping of the right atrium, right ventricle, left atrium and left ventricle of the heart.

The findings met all Study Endpoints concerning safety and performance of the CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath:

1) No damage or product integrity issues related to CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath.
2) No leakage through hemostatic valve.
3) No thrombus observed inside or at the tip of the sheath.
4) No clinically significant tissue injury related to the use of the Test article.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is substantially equivalent to its currently cleared predicate based on the successful completion of nonclinical bench testing and pre-clinical studies, as well as the technological comparison exhibiting similar principles of design, operation, and indications for use.