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NOV 21 2001

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a Johnson & Johnson company

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510(k) summary for the CARTO™ XP Mapping System

510(k) Notification submitted by:	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765 USA Phone: +1-800-729-9010 Fax: +1-909-839-8804
Contact person:	Amy Walters Director of Regulatory and Clinical Affairs
Proprietary device name:	CARTO™ XP EP Navigation System
Classification name:	Programmable diagnostic computer (per 21 CFR 870.1425)
Common device name:	Cardiac mapping system
Predicate device:	CARTO™ mapping system 510(k) No. K000248
Manufacturer:	Biosense Webster (Israel) Ltd. POB 2009 Tirat HaCarmel, 39120 Israel

The CARTO™ XP mapping system is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. In the CARTO XP mapping system the location information needed to create the cardiac maps is acquired using locatable-tip catheters equipped with a magnetic location sensor.

Cardiac EP mapping procedures are generally performed using a roving mapping catheter, a computerized mapping system, and fluoroscopy to determine the location of the tip of the mapping catheter. In the conventional procedure both the patient and the physician are exposed to harmful ionizing radiation during the course of the lengthy procedure. The CARTO mapping system enables cardiac mapping using a magnetic location technology, and may reduce exposure to dangerous ionizing radiation.

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The CARTO™ XP mapping system complies with the following safety standards:

- UL 2601-1:97/ CSA-C22.2 No. 601.1
- IEC 60601-2-25:93+A1(99)
- IEC 60601-2-27:94

The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed device to which it is being compared and does not raise any new questions of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Ms. Amy Walters
Director, Regulatory and Clinical Affairs
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K013083
Trade Name: Carto™ XP EP Navigation System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 19, 2001
Received: October 23, 2001

Dear Ms. Walters:

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.

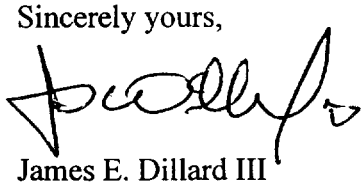
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for use statement

510(k) No: K013083

Device Name: CARTO™ XP mapping system

Indications For Use:

The intended use of the CARTO XP mapping system is catheter-based atrial and ventricular mapping.

The CARTO XP mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps and cardiac impedance maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013083

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