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15 510(k) Summary

15.1 Sponsor's Name & Address

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

15.2 Official Correspondent

Melissa C. Schultz
Senior Specialist, Regulatory Affairs
Phone: 909-839-8787
Fax: 909-839-8804
Email: MSchult1@its.jnj.com

15.3 Submission Date

July 7, 2009

15.4 Trade Name

SOUNDSTAR 3D Ultrasound Catheter

15.5 Common Name

Electrophysiology Mapping/Ultrasound Catheter

15.6 Classification Name/Product Code

Intravascular Ultrasound Catheter/OBJ

15.7 Classification

Class II

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15.8 PREDICATE DEVICE

The modified SOUNDSTAR 3D Ultrasound Catheter is substantially equivalent to the SOUNDSTAR 3D Ultrasound Catheter (510(k) K070242) cleared on May 15, 2007, and also to the ACUSON ACUNAV 10F Diagnostic Ultrasound Catheter (510(k) K071234) cleared on June 29, 2007.

15.9 DESCRIPTION OF MODIFIED DEVICE

The modified Biosense Webster SOUNDSTAR Catheter is a 90 cm 10F IntraCardiac Echo (ICE) Catheter with an acoustic array identical to the currently cleared Biosense Webster SOUNDSTAR Catheter and the ACUSON ACUNAV 10F Diagnostic Ultrasound Catheter. The modified SOUNDSTAR Catheter has a location sensor (providing location information to CARTO XP EP Navigation System, Version 9.7 or greater) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip.

The modified SOUNDSTAR Catheter has a bifurcated 'tail' originating from its handle. One leg terminates in the SOUNDSTAR Flex Tab connector, which connects via a SwiftLink cable to the GE Vivid-i or Vivid-q Ultrasound System. The other leg terminates in the CARTO Hypertronic connector, which connects via a Patient Interface Unit (PIU) extension cable to the CARTO Navigation System.

The modified SOUNDSTAR Catheter, when connected to the CARTO XP EP Navigation System, Version 9.7 or greater, and the GE Vivid-i or Vivid-q Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO electromagnetic acquired maps.

15.10 INDICATIONS FOR USE

The Biosense Webster SOUNDSTAR 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the CARTO XP EP Navigation System, Version 9.7 or greater, the SOUNDSTAR 3D Catheter provides location information.

15.11 DESCRIPTION OF MODIFICATION

The modified SOUNDSTAR Catheter is physically ***identical*** to the currently cleared SOUNDSTAR Catheter in terms of design, manufacturing methods, materials and performance. The only modifications were made to the Indications for Use, identification code on the catheter Flex Tab connector, and also to the labeling for the device. Specifically, the Flex Tab connector of the modified SOUNDSTAR Catheter has been modified to include a different identification code so that the modified catheter may

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only be compatible with the GE Vivid-i and Vivid-q Ultrasound Systems. The modification to the labeling was to include reference of the new GE Vivid-i and Vivid-q Ultrasound Systems in the Instructions for Use, and to provide version specificity of the CARTO System (Version 9.7 or greater) which the modified SOUNDSTAR Catheter has been validated with. Additionally, the package label of the modified SOUNDSTAR Catheter will be a different color from the currently cleared SOUNDSTAR Catheter and will include the statement "Not For Use on Siemens Systems". The purpose for this labeling change will enable users to differentiate between the modified SOUNDSTAR Catheter and the currently cleared SOUNDSTAR Catheter.

15.12 SUMMARY OF NONCLINICAL TESTS

All testing previously submitted for the currently cleared SOUNDSTAR Catheter still applies to the modified device as there were no changes to the design, materials, manufacturing methods or performance of the device. Testing for compatibility with the GE Vivid-i and Vivid-q Ultrasound Systems in conjunction with the CARTO XP EP Navigation System Version 9.7 was conducted and all tests met the pre-determined specifications for the SOUNDSTAR Catheter, GE Vivid-i and Vivid-q Ultrasound Systems, and the CARTO System. Please reference the Special 510(k) submission for the GE Vivid-i and Vivid-q Ultrasound Systems (which will be submitted by the end of July 2009), for details regarding systems interface testing.

15.13 SUBSTANTIAL EQUIVALENCE CONCLUSION

The modified SOUNDSTAR Catheter is identical to the currently cleared SOUNDSTAR Catheter in that both of the devices:

- have the same intended use
- use the same operating principle
- use the same fundamental scientific technology
- incorporate the same design
- incorporate the same materials and construction
- have the same shelf life
- are packaged using the same materials and processes
- have the identical Hypertronic connector
- use the identical interface cable for connection to CARTO
- have the same 64-channel acoustic phased array
- have the same acoustic array location and connection
- have the same distal tip material and deflection mechanism
- have the same shaft material
- are radiopaque

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- are EtO sterilized
- are single use devices

With regards to the ACUNAV predicate device, both the modified SOUNDSTAR Catheter and the ACUNAV Catheter compatible with GE Ultrasound Systems:

- have the identical identification code in the catheter Flex Tab connector to allow compatibility with the GE Ultrasound Systems
- connect to the identical SwiftLink cable which allows interface with the GE Vivid-i and Vivid-q Ultrasound Systems
- have the same 64-channel acoustic phased array
- have the same acoustic array location and connection
- have the same distal tip material and deflection mechanism
- have the same shaft material
- are radiopaque
- are EtO sterilized
- are single use devices

In summary, the modified SOUNDSTAR Catheter described in this submission is substantially equivalent to the currently cleared SOUNDSTAR Catheter and the ACUNAV Catheter predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 07 2009

Biosense Webster, Inc.
Melissa C. Schultz, MMS, Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K092064
Trade/Device Name: SoundStar 3D Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: July 7, 2009
Received: July 8, 2009

Dear Ms. Schultz:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Donna R. Kahner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications for Use

510(k) No (if known): K092064

Device Name: SOUNDSTAR 3D Ultrasound Catheter

Indications for Use:

The Biosense Webster SOUNDSTAR 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the CARTO XP EP Navigation System, Version 9.7 or greater, the SOUNDSTAR 3D Catheter provides location information.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092064