K101419
p1/3

12 510(k) Summary for Public Disclosure

JUN 11 2010

12.1 Submitter's Name/Contact Person

Donna R. Lunak
St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117 USA

The Establishment Registration Number is 2184149.

12.2 Common or Usual Name

Electrophysiology Mapping System with console and catheter

12.3 Proprietary Name

EnSite Velocity System
Consisting of:
EnSite Multi-electrode Diagnostic Catheter (EnSite Array™ – Model EC1000)
EnSite Electrophysiology Workstation – Model EE3000
EnSite NavX Surface Electrode Kit – Model EN0010

12.4 Classification Name

DQK, Programmable diagnostic computer (21 CFR 870.1425), Class II,
Circulatory Systems Device Panel

12.5 Hardware Description

The EnSite Velocity System consists of the following:

- Display Workstation
- Amplifier

12.6 Indications for Use

The EnSite Velocity™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies are indicated.

- When used with the EnSite Array™ Catheter, the EnSite System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

OR

- When used with the EnSite NavX Surface Electrode Kit, the EnSite System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.

12.7 Device Comparison to the Predicate Device

The EnSite Velocity System with EnSite Courier™ has the same intended use and fundamental scientific technology as the predicate device, EnSite Velocity System v.1.3 (K093942). All technological characteristics of the EnSite Velocity System with EnSite Courier™ are substantially equivalent to the predicate device, EnSite Velocity System v.1.3 (K093942).

12.8 DICOM Conformance Statement

The EnSite Velocity System with EnSite Courier ™ conforms to the ACR-NEMA Digital Imaging and Communications in Medicine (DICOM) standard. A DICOM Conformance Statement is presented in Appendix R.

12.9 Summary of Non-Clinical Testing

Bench testing was performed to confirm that the changes met design requirements and did not affect the safety or effectiveness of the product.

12.10 Summary of Clinical Testing

Cross-vendor interoperability testing sessions were conducted between EnSite Courier and 15 different PACS models/versions, seven vendors. This clinical test report can be found in Appendix S.

12.11 Summary of Design Control Activities

The development of the EnSite Networking Software Feature – EnSite Courier™ was performed in accordance with St. Jude Medical's Quality System requirements, and in compliance with Quality System Regulation design controls

requirements documented in 21 CFR 820.30. A Declaration of Conformity with Design Controls follows in section 13.4.

12.12 Conclusion

The EnSite Velocity System with EnSite Courier ™ has the same indications for use, intended use and fundamental scientific technology as the predicate device. All technological characteristics of the EnSite Velocity System with EnSite Courier ™ are substantially equivalent to the predicate device, EnSite Velocity System v.1.3 (K093942).

Where operational and performance differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the device's safety and effectiveness.

Therefore, St. Jude Medical considers the EnSite Velocity System to be substantially equivalent to the predicate device, EnSite Velocity System v.1.3 (K093942).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 11 2010

St. Jude Medical
c/o Ms. Donna Lunak
Regulatory Specialist II
One St. Jude Medical Drive
Saint Paul, MN 55117

Re: K101419
Trade/Device Name: EnSite Velocity System
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: DQK
Dated: May 19, 2010
Received: May 20, 2010

Dear Ms. Lunak:

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,

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

Enclosure

K101419

7 Indications for Use

Device Name: EnSite Velocity System

Indications for Use:

The EnSite Velocity™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies are indicated.

- When used with the EnSite Array™ Catheter, the EnSite System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

OR

- When used with the EnSite NavX Surface Electrode Kit, the EnSite System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101419