

**510(k) Summary for Public Disclosure**

- Submitter:** St. Jude Medical  
1350 Energy Lane, Suite 110  
St. Paul, MN 55108 USA  
Phone: 651-523-6900  
Fax: 651-644-7897
- Contact:** Karen J. McKelvey  
Principal Regulatory Compliance Engineer
- Date Prepared:** March 21, 2007
- Trade Name:** EnSite<sup>®</sup> System (Model EE3000)  
a) EnSite<sup>™</sup> Array (Model EC1000)  
b) EnSite NavX<sup>™</sup> Surface Electrode Kit (Model EN0010)  
d) EnSite Verismo<sup>™</sup> Segmentation Tool (Model EV1000)
- Common name:** Electrophysiology cardiac mapping system
- Classification Name:** a) Electrode recording catheter or electrode recording probe (21CFR 870.1220)  
b) Programmable diagnostic computer (21 CFR 870.1425)
- Predicate Device:** EnSite System  
510(k) No. K060954
- Device Description:** The EnSite System is a computerized storage and display system for use in electrophysiology studies of the human heart. The system consists of a console workstation, patient interface unit, and an electrophysiology mapping catheter or surface electrode kit.
- Unlike currently available electrode recording catheters, the EnSite Array does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite System is a system that facilitates mapping and treatment of arrhythmias. When used with the EnSite catheter, the system is useful for treating patients with complex, non-sustained, or poorly tolerated

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arrhythmias that are difficult, if not impossible, to map with current mapping techniques. By visualizing the global activation pattern seen on the color-coded isopotential maps in the EnSite System, in conjunction with the reconstructed electrograms, the electrophysiologist can identify the arrhythmia source and can navigate to the defined area for therapy. When used with NavX patches, the system is useful in treating patients with simpler arrhythmias by providing non-fluoroscopic navigation and visualization of conventional EP catheters

Intended use: The EnSite System (EE3000) is indicated for patients for whom electrophysiology studies are indicated.

- When used with the EnSite Array, 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 catheters in the heart.

Technological  
Characteristics:

The new device has the same technological characteristics as the legally marketed predicate device.

Non-clinical  
Performance Data:

The changes made to the EnSite System underwent a battery of bench and user tests. Device validation testing was conducted in accordance with in-house procedures.

Conclusion:

An evaluation of the device changes indicates that the device is as safe and effective as the previously marketed device to which it is being compared and does not raise any new issues of safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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St. Jude Medical  
Ms. Karen J. McKelvey  
Principal Regulatory Compliance Engineer  
1350 Energy Lane, Suite 110  
St. Paul, MN 55108

Re: K070902

Trade Name: EnSite™ System v7.0

Regulation Number: 21 CFR 870.1425 and 870.1220

Regulation Name: Programmable Diagnostic Computer And Electrode Recording Catheter  
Or Electrode Recording Probe

Regulatory Class: Class II

Product Code: DQK and DRF

Dated: March 30, 2007

Received: April 2, 2007

Dear Ms. McKelvey:

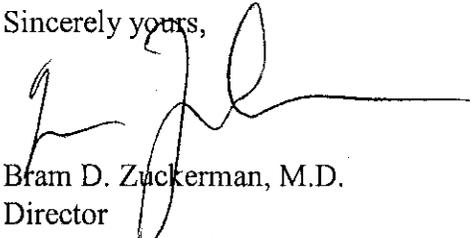
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number (if known): K070902

Device Name: EnSite System

### Indications For Use:

The EnSite System is indicated for patients for whom electrophysiology studies are indicated.

- When used with the EnSite™ 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 catheters in the heart.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division of Cardiovascular Devices)  
Division of Cardiovascular Devices  
510(k) Number K070902

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