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ENDOCARDIAL SOLUTIONS

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SEP 2 8 2001

510(k) Summary

Submitter: Endocardial Solutions
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Contact: Eric W. Koehler
Director of Clinical and Regulatory Affairs

Date Prepared: August 30, 2001

Trade Name: EnSite 3000® System

a) Model EC 1000 EnSite® Multi-electrode Diagnostic Catheter
b) EnSite 3000® Electrophysiology Workstation

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: Endocardial Solutions EnSite 3000 System
510(k) No. K001437

Device Description:

The EnSite 3000 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.

Unlike currently available electrode recording catheters, the EnSite Catheter does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite 3000 Electrophysiology Workstation connected to the EnSite Catheter utilizes proprietary software algorithms to reconstruct and display right atrial electrograms detected by the EnSite Catheter. This information can be presented as color-coded three-dimensional maps to provide global electrical activation patterns of the heart

chamber. The EnSite 3000 System may also be used in conjunction with standard electrode mapping catheters, programmable cardiac stimulators, ECG leads, and other analog or digital inputs.

The EnSite 3000 System also incorporates a navigational tool to provide real-time feedback regarding the position of an auxiliary catheter for creation of a geometrical model of the heart chamber or for guiding therapy to a designated location.

Intended use:

The EnSite Multi-electrode Diagnostic Catheter used with the EnSite 3000 Electrophysiology Workstation 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 (i.e., linear mapping catheters).

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 3000 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Mr. Eric W. Koehler
Endocardial Solutions, Inc.
1350 Energy Lane, Suite 110
St. Paul, MN 55108-5254

Re: K012926
Trade Name: Endocardial Solutions EnSite 3000 System
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: MTD
Dated: August 30, 2001
Received: August 31, 2001

Dear Mr. Koehler:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

The warning should appear in a black box, and the font size of the text should be at least 2 points larger than any surrounding text. The Warning should be present on the first page of your Catheter Instructions for Use and on the packaging for each individual catheter.

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); 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.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 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"(21 CFR 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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012926

Device Name: Ensite® 3000 System

FDA's Statement of the Indications For Use for device:

The Ensite® Multi-electrode Diagnostic Catheter used with the Ensite 3000 Electrophysiology Workstation 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 (i.e., linear mapping catheters).

Division of Cardiovascular & Respiratory Devices
510(k) Number K012926

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)