

4/21/99

510(k) Notification

K983456

18. CERTIFICATIONS AND SUMMARIES

18.1 Summary for Public Disclosure

510(k) Summary

Submitter: Andrew Balo
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Contact: Andrew Balo
Vice President Regulatory Affairs, Quality Assurance, Clinical Affairs

Date Prepared: September 25, 1998

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

- a) Electrode recording catheter or electrode recording probe
(21CFR 870.1220)
- b) Programmable diagnostic computer (21 CFR 870.1425)

- Equivalence to:**
- a) EP Technologies, Inc. Asymmetric Curve Stereocath and other similar recording catheters.
 - b) Biosense CARTO System and other similar programmable diagnostic computer

Description: EnSite 3000 System Components

EnSite Multi-electrode Diagnostic Catheter

The EnSite Multi-electrode Diagnostic Catheter (EnSite catheter) is a single use, 9 French, percutaneous catheter. The EnSite catheter is designed for use only with the EnSite 3000 electrophysiology laboratory and for deployment in the right atrium. The proximal end contains the patient cable electrical connector, an inflation port for the distal balloon/braid multi-electrode array (MEA), luer port compatible with a 0.035" guidewire, and a push shaft to facilitate expansion and deployment of the MEA. The shaft is a coaxial design with a polyurethane outer sheath. At

the distal end in addition to the MEA, there are three ring electrodes, one distal and two proximal mounted at specific locations to the MEA. The tip of the catheter is a pigtail shape to minimize trauma to the endocardium. Biocompatible materials are used for all blood contacting surfaces.

EnSite 3000 electrophysiology workstation

The EnSite 3000 electrophysiology workstation is a computerized storage and display system for use in electrophysiology studies of the human heart. It is designed for use in the EP laboratory with the EnSite Multi-electrode Diagnostic Catheter and in conjunction with other standard equipment found in the EP laboratory. This allows for the collection, storage, and display of intracardiac electrograms. The EnSite 3000 may be used in conjunction with standard electrode mapping catheters, programmable cardiac stimulators, ECG leads and other analog inputs.

The EnSite 3000 is comprised of a display workstation consisting of a Silicon Graphics Octane processor containing proprietary software and a 21" monitor and a Patient Interface Unit which accepts the signals from the patient and from other accessories and converts them to digital signal and sends them to the display workstation for processing.

Intended use:

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. contact mapping catheters)

Technological Characteristics:

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 connected to the EnSite catheter utilizes proprietary software algorithms to reconstruct and display right atrial endocardiograms detected by the EnSite catheters MEA.

Non-clinical performance data:

The EnSite catheter underwent a battery of in vitro tests including tensile, torsion, inflation, deflation testing. Biocompatibility was confirmed in accordance with ISO 10993.

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The EnSite 3000 was tested and conforms to IEC 601-1 and IEC 601-2-27 international standards. Device validation testing was conducted in accordance with in house procedures.

Animal studies were utilized to show initial catheter and system safety of the catheter.

Clinical Data:

Clinical studies were conducted which demonstrate that the EnSite 3000 System is as safe and effective as EP mapping catheter systems presently marketed. The results indicate that it can map complex atrial arrhythmias.

Conclusion:

An evaluation of the predicate devices, in vitro testing, animal testing and human clinical testing shows that the EnSite 3000 and the EnSite Multi-electrode Diagnostic Catheter are substantially equivalent to currently marketed programmable diagnostic computers and electrode recording catheters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1999

Mr. Andrew Balo
Vice President, Regulatory,
Clinical Affairs and Quality Assurance
Endocardial Solutions, Inc.
1350 Energy Lane, Suite 110
Saint Paul, MN 55108-5254

Re: K983456
EnSite™ Multi-Electrode Diagnostic Catheter and
EnSite 3000™ Electrophysiology Workstation
Regulatory Class: II (two)
Product Code: MTD, DQK
Dated: January 29, 1999
Received: January 29, 1999

Dear Mr. Balo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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(1)(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 a 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 must 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

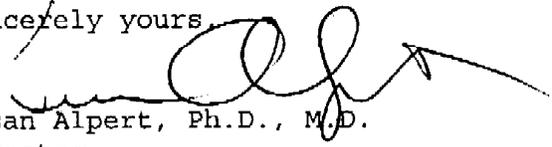
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if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

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If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink, appearing to read 'Susan Alpert', with a long horizontal stroke extending to the right.

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K983456.

Device Name: EnSite™ Multi-Electrode Diagnostic Catheter and EnSite 3000™ Electrophysiology Workstation

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).

Prescription Use 
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983456