

DEC - 2 1999

**510(k) Summary**

**Submitter:** James W. Bullock  
 President and CEO  
 Endocardial Solutions  
 1350 Energy Lane, Suite 110  
 St. Paul, MN 55108

**Contact:** James W. Bullock  
 President and CEO

**Date Prepared:** July 22, 1999

**Trade Name:** EnSite 3000<sup>®</sup> System

- a) Model EC 1000 EnSite<sup>®</sup> Multi-electrode Diagnostic Catheter
- b) EnSite 3000<sup>®</sup> 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) Endocardial Solutions EnSite 3000<sup>®</sup> System

**Description:** EnSite 3000<sup>®</sup> System Components

EnSite<sup>®</sup> Multi-electrode Diagnostic Catheter

The EnSite<sup>®</sup> Multi-electrode Diagnostic Catheter (EnSite<sup>®</sup> catheter) is a single use, 9 French, percutaneous catheter. The EnSite<sup>®</sup> catheter is designed for use only with the EnSite 3000<sup>®</sup> System in an 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<sup>®</sup> Electrophysiology Workstation

The EnSite 3000<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> may be used in conjunction with standard electrode mapping catheters, programmable cardiac stimulators, ECG leads and other analog inputs.

The EnSite 3000<sup>®</sup> System 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:

The EnSite<sup>®</sup> Multi-electrode Diagnostic Catheter used with the EnSite 3000<sup>®</sup> 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:

Unlike currently available electrode recording catheters, the EnSite<sup>®</sup> catheter does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite 3000<sup>®</sup> Electrophysiology Workstation connected to the EnSite<sup>®</sup> catheter utilizes proprietary software algorithms to reconstruct and display right atrial endocardiograms detected by the EnSite<sup>®</sup> catheter's MEA.

#### Non-clinical performance data:

The changes made to the 3000<sup>®</sup> 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 this EnSite 3000<sup>®</sup> System is substantially equivalent to the currently marketed system.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 2 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. James W. Bullock  
President and Chief Executive Officer  
Endocardial Solutions, Inc.  
1350 Energy Lane, Suite 110  
Saint Paul, MN 55108-5254

Re: K992479  
Trade Name: EnSite™ Multi-Electrode Diagnostic Catheter and  
EnSite 3000™ Electrophysiology Workstation  
Regulatory Class: II (two)  
Product Code: MTD, DQK  
Dated: October 15, 1999  
Received: October 15, 1999

Dear Mr. Bullock:

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(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 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

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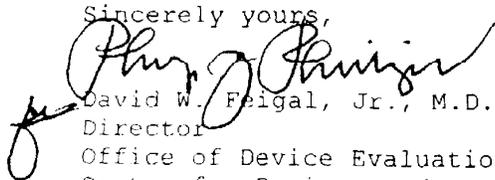
can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) 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.

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,



David W. Feigal, Jr., M.D., M.P.H.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) K992479.

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).

Nancy C Brogdon  
(Division Sign/Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K992479

Prescription Use xx OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)