

APPENDIX G: Premarket Notification (510(K)) Summary For Public Disclosure

- Submitter:** Endocardial Solutions, Inc.
1350 Energy Lane, Suite 110
St. Paul, MN 55108
- Contact:** James W. Bullock, President and Chief Executive Officer
- Date Prepared:** October 4, 1999
- Trade Name:** EnSylet™ Model EC0010/20
- Common Name:** Stylet, Catheter Stylet
- Equivalence to:** Intermedics Stylets Models 365-81, 365-82, 365-89, 365-90, and Pacesetter Locator Steerable Stylet Model 4036
- Description:** The EnSylet™ EC0010/20 is a pre-formed J-shaped or straight, ball-tipped, 0.027-inch diameter stainless steel wire designed to be used in conjunction with the EnSite® EC1000 catheter during electrophysiologic mapping procedures using the EnSite 3000® System.
- Intended Use:** The EnSylet™ EC0010/20 is intended for use in conjunction with the EnSite® EC1000 catheter during electrophysiologic mapping procedures using the EnSite 3000® System. The EnSylet™ is designed to provide deflection and positioning of the distal end of the catheter.
- Technological Characteristics:**
Comparisons between the new and predicate devices shows that technological characteristics (i.e. device design, materials, and components) and indications for use for the EnSylet™ are equivalent to the currently marketed predicate devices.
- Non-Clinical Data:** The EnSylet™ was subjected to extensive in vitro testing demonstrating that the stylet met or exceeded all dimensional, mechanical, and functional specifications. The performance of the EnSylet™ was found to be acceptable for its intended use.
- Conclusion:** The EnSylet™ was found to be equivalent to technological characteristics and indications for use for the predicate devices. Extensive in vitro testing demonstrated the performance of the EnSylet™ to be acceptable for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993376
EnSylet™ Model EC0010/20
Regulatory Class: II (two)
Product Code: DRB
Dated: October 4, 1999
Received: October 7, 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. 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.

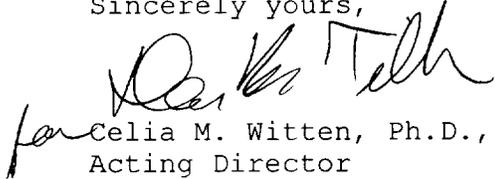
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21CFR 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 "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular,

Respiratory, and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

9.0 INDICATIONS FOR USE

The EnStylet™ EC0010/20 is intended for use in conjunction with the EnSite® EC1000 catheter during electrophysiologic mapping procedures using the EnSite 3000® System. The EnStylet™ is designed to provide deflection and positioning of the distal end of the catheter.

for Dan K. Tull

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993376

Prescription Use X
(Per 21 CFR 801.109)