K982415

AUG 10 1998

Appendix A: 510(k) Summary of Safety and Effectiveness

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The REF-STAR External Reference Patch (ERP) is an integral part of a non-fluoroscopic catheter tip location and electrogram capture technology called CARTO and NOGA. When used with the CARTO and NOGA systems, the intracardiac location of the NAVI-STAR or NOGA-STAR mapping catheter tip is compared to the location of this reference patch. This reference device consists of a sensor embedded in an adhesive patch, which is connected to an handle that houses the printed circuit board.

The ERP, like the Predicate Device the Ex Surface Reference Device, is an external device placed on the patient's back by an adhesive patch. The adhesive patch is located on the distal end of the reference device and sandwiches a Biosensor in-between two hypoallergenic adhesive foam pads. The patch is permanently fixed to the shaft and acts as protection for the Biosensor in addition to providing a way to attach the sensor to the patient. The shaft is an Estane material which is radiolucent and houses the electrical cables for the Biosensor. The Biosensor is connected to a PC board which amplifies the electrical signal before it is transferred to the CARTO or NOGA system. The PC board also contains calibration data for the X, Y and Z axis of the sensor. The strain relief for the shaft as it enters the Barrel Cone is made up of two layers of Polyolefin heat shrink tubing. The Barrel Cone is made of Delrin and is attached to the Barrel Extension which is also made of Delrin. The Barrel Extension houses the PC board and connector. The PC board is surrounded by a Mu Metal Shield to protect it from electromagnetic interference.

Intended use

The intended use of the New Device is to provide a reference location relative to the mapping/diagnostic catheter when used in conjunction with the CARTO and NOGA equipment.

Continued on next page

Indications statement	The Cordis Webster REF-STAR External Reference Patch is indicated for the use with the NAVI-STAR and NOGA-STAR catheters and the CARTO and NOGA systems to provide catheter tip location as well as electrogram information.
Technological characteristics	The technological characteristics of the New Device are the same as the Predicate Device.
Performance data	Verification testing of the New Device was conducted to verify the structural integrity, electrical integrity and adhesive durability of the External Reference Patch and to compare the applicable results to the Predicate Device.
Conclusion	Based on the 510(k) summaries and the 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.
Contact	Mary Adams Regulatory Affairs Manager Cordis Webster, Inc. 4750 Littlejohn Street Baldwin Park, CA 91706
Date	July 10, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Adams
Regulatory Affairs Manager
Cordis Webster, Inc.
4750 Littlejohn Street
Baldwin Park, CA 91706

AUG 10 1998

Re: K982415
Cordis Webster REF-STAR™ External Reference Patch
Regulatory Class: II (two)
Product Code: DRF
Dated: July 10, 1998
Received: July 13, 1998

Dear Ms. Adams:

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.

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,

for Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

510(k) Number: K 982415

Device Name: REF-STAR External Reference Patch

Indications for Use: The REF-STAR External Reference Patch is indicated for use with the NAVI-STAR and NOGA-STAR catheters and the CARTO and NOGA systems to provide catheter tip location as well as electrogram information.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982415