

K980961

MAY 28 1998

510(k) SUMMARY

March 13, 1998

Prepared by: Cordis Webster, Inc.
4750 Littlejohn Street
Baldwin Park, CA 91706
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Contact Person: Mary Adams
Regulatory Affairs

510(k) Summary

Classification Name None
Common/Usual Name: Surface Reference Device
Proprietary Name: Cordis Webster REF-STAR Ex Surface Reference Device

Name of Predicate Devices

Cordis Webster REF-STAR Catheter

Device Description

The Cordis Webster REF-STAR Ex Surface Reference Device has been designed to be placed externally on the patient's back in order to compensate for movement during electrophysiological and electromechanical mapping of the heart. The Cordis Webster REF-STAR Ex Surface Reference is an integral part of a non-fluoroscopic catheter tip location and electrogram capture technology known as CARTO™ and NOGA™. When used with the CARTO and NOGA system, the location of the mapping catheter tip, the NAVI-STAR, NOGA-STAR or REF-STAR is compared to the location of the reference device. This reference device consists of a sensor embedded in a polyurethane shaft, which is connected to a handle that houses the printed circuit board.

Intended Use

The Cordis Webster REF-STAR Ex Surface Reference Device is indicated for use with the NAVI-STAR, NOGA-STAR or REF-STAR catheters and the CARTO and NOGA system to provide catheter tip location.

Technological Characteristics

The subject device is technologically equivalent to the predicate device, the Cordis Webster REF-STAR catheter. Both the subject and marketed devices facilitate electrophysiology mapping. There are no known or suspected new or different implications with respect to safety or effectiveness relative to the changes made for this device.

510(k) Summary (continued)

Performance Data (Nonclinical Testing)

The nonclinical performance testing conducted on REF-STAR Ex Surface Reference Device compared to the predicate device indicated that there was no significant differences in the outcome of the tests for each of the devices that would affect the safety and effectiveness of the device. The applicable tests were performed according to FDA's "Electrode Recording Catheter Preliminary Guidance".

Conclusions Drawn from the Nonclinical Tests

The results of the nonclinical performance tests indicate that REF-STAR Ex Surface Reference Device performs as well as the currently marketed device and that the differences in testing outcome are not significant; therefore, Cordis Webster concludes that REF-STAR Ex Surface Reference Device is substantially equivalent to the currently marketed device, the Cordis Webster REF-STAR catheter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1998

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

Re: K980961
Cordis Webster REF-STAR® Ex Surface Reference Device
Regulatory Class: II (two)
Product Code: DRF
Dated: March 13, 1998
Received: March 16, 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 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" (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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

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

Enclosure

510(k) Number (if known): TO BE ASSIGNED

Device Name: CORDIS WEBSTER REF-STAR®
EX SURFACE REFERENCE DEVICE

Indications for Use:

The Cordis Webster REF-STAR Ex Surface Reference Device is indicated for use with the NAVI-STAR®, NOGA-STAR™, or REF-STAR catheters and the CARTO™ and NOGA™ systems to provide catheter tip location.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K980961