OCT 4 1999

K991531

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 Diagnostic Deflectable Tip Catheter (5 French size) modification is applicable only to the Instructions for Use. The function, component materials, and intended use of the Diagnostic Deflectable Tip Catheter as compared to the Predicate Device (of the same name - K892265) are identical. An additional indication for use and warning are added that allows the use of the catheter to not only be used in adults but in children 4 years of age and older. The additional warning is to alert the physician regarding the possibility of brachial plexus injury. These additions to the IFU were requested by FDA on behalf of P950005/S3, the pediatric indication approval for Cordis Webster's Diagnostic/Ablation Deflectable Tip Catheters, 6 and 7 French. They also apply to the 5 French diagnostic catheter. The safety or effectiveness of the subject device was not affected as the device itself has not been altered.

The Diagnostic Deflectable Tip Catheter (5 French size) is essentially a smaller diameter version of the Premarket Notified 6, 7 French design. These catheters were designed to facilitate electrophysiological mapping of the heart. The catheter has a high-torque shaft with a deflectable tip section containing platinum electrodes that can be used for stimulation and recording.

The 5 French Deflectable Catheter utilized the same design features that are in the present deflectable catheter with the exception of the tip electrode connection/termination method. The electrical connection is made in the same way as is done with the Predicate Device, however, the puller-wire which is normally anchored proximal to the tip is terminated (soldered) directly to the tip electrode. Since the puller-wire is attached to the tip electrode, the puller-wire replaces the safety wires that were in the 6 and 7 French Deflectable Catheters. This tip electrode connection/termination method is also utilized for the Crista Cath™ diagnostic catheter approved under K953768.

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

Intended use	The intended use of the Diagnostic Deflectable Tip Catheter is to map cardiac structures using stimulation and recording techniques.
Indications statement	The Cordis Webster Diagnostic Deflectable Tip Catheter is indicated for electrophysiology mapping of cardiac structures in adults and children 4 years of age and older; i.e. stimulation and recording only.
Technological characteristics	The technological characteristics of the Modified Device are the same as the Predicate Device.
Performance data	Performance data was provided as the number of complaints versus the number of units sold. Further related published literature was cited to show the safety and effectiveness of the smaller french size catheter used in pediatric patients. A process capability study is referenced which is applicable to all puller wires that are attached directly into the stem of the tip electrode for deflectable catheters. The pull tests that were conducted resulted in high capability indices. Based on these results, the process for soldering puller wires to the tip electrode was found to be more than capable.
Conclusion	Based on the 510(k) summaries and the 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the Modified 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	April 30, 1999

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 1999

Ms. Mary Adams
Cordis Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K991531/S1
Cordis Webster Diagnostic Deflectable Tip Catheter
Regulatory Class: II (two)
Product Code: 74DRF
Dated: August 27, 1999
Received: August 30, 1999

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,

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): K991531

Device Name: Diagnostic Deflectable Tip Catheter

Indications For Use: The Cordis Webster Diagnostic Deflectable Tip Catheter is indicated for electrophysiology mapping of cardiac structures in adults and children 4 years of age and older; i.e., stimulation and recording only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991531

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)