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

Intended use	The intended use of the Fixed Curve Catheter is to map cardiac structures using stimulation and recording techniques.
Indications statement	The Cordis Webster Fixed Curve 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 Subject device have not changed due to the addition of the pediatric indication.
Performance data	Capability testing was performed to ensure adequate pull strength. All samples passed the acceptance criteria. Performance data was provided as the number of complaints versus the number of units sold. Further, three letters from physicians were included as they discuss their clinical experience with the absence of adverse events by using smaller French size catheters in pediatric patients.
Conclusion	Based on the 510(k) summaries and the 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the Subject device is substantially equivalent to the same 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	September 1, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1999

Ms. Nanette Canepa
Regulatory Affairs Associate
Cordis Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K992965
Cordis Webster Fixed Curve Catheters
Regulatory Class: II (two)
Product Code: DRF
Dated: September 1, 1999
Received: September 2, 1999

Dear Ms. Canepa:

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

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

Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

510(k) Number: K 992965

Device Name: Fixed Curve Catheter

Indications for Use: The Cordis Webster Fixed Curve 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.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992965

Prescription Use X
(Per 21 CFR 801.109)