

OCT 28 1997

510(k) Summary**Classification Name**

Common/Usual Name: Introducer

Proprietary Name: Cordis Webster Braided Guiding Sheath Exchange System

Name of Predicate DeviceCordis 9 FR Guiding Catheter
Daig Fast-Cath™ Hemostasis Introducer**Device Description**

The Cordis Webster Braided Guiding Sheath Exchange System consists of guiding sheaths with a sideport and valve, pre-shaped distal tip section with radiopaque brite tip, a guidewire, a conventional vessel dilator, and a long tapered exchange vessel dilator with a multipurpose curve at the distal end.

The guiding sheaths have large non-tapered lumens that allow for intravascular passage of catheters and infusion of heparinized normal saline and/or contrast medium. The guiding sheaths feature a nylon body reinforced with a tightly wound stainless steel braid wire. The braid wire extends from the proximal hub through several flexible transition segments to the "brite tip" which is a low durometer Polyurethane with radiopaque filler at the distal end.

The transition segments are comprised of several durometers of material designed to vary the stiffness along the entire length of the guiding sheath shaft. The higher durometer is used on the proximal segment of the shaft to yield a stiffer segment. This stiffer segment provides the added support required to manipulate the guiding sheath during cannulation. The distal transition segments utilize an increasingly softer durometer which provides the flexible atraumatic distal tip segment.

510(k) Summary (continued)

Intended Use

The intended use of the percutaneous Braided Guiding Sheath Exchange System is for the introduction of intravascular electrophysiology catheters into any cardiac chamber.

Technological Characteristics

The Cordis Webster Braided Guiding Sheath Exchange System and the Cordis Guiding Catheter, one of the predicate devices, consist of the same components, with exception of the multipurpose curve (i.e. shaped section of the vessel dilator) and a shorter sheath length to assist physician technique.

Performance Data (Nonclinical Testing)

The nonclinical performance testing conducted on the Cordis Webster Braided Guiding Sheath Exchange System compared to the predicate devices indicated that there were no significant differences in the outcome of the tests for each of the devices that would affect the safety and effectiveness of the device.

Conclusions Drawn from the Nonclinical Tests

The results of the nonclinical performance tests indicate that the Cordis Webster Braided Guiding Sheath Exchange System performs as well as the predicate devices and that the differences in testing outcome are not significant; therefore, Cordis Webster concludes that the Cordis Webster Braided Guiding Sheath Exchange System is substantially equivalent to the predicate devices, the 9F Cordis Guiding Catheter and the Daig Fast-Cath™ Hemostasis Introducer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT 28 1997

Re: K970264
Trade Name: Cordis Webster Braided Guiding
Sheath Exchange System
Regulatory Class: Two (II)
Product Code: 74DYB
Dated: July 22, 1997
Received: July 23, 1997

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 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 (Pre-market 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

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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,



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

510(K) Number (if known): K970264

Device Name: Cordis Webster Braided Guiding Sheath Exchange System

Indications for Use:

Introduction of intravascular electrophysiology catheters into any cardiac chamber.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 D. M. Tullin
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970264