K982740

AUG 28 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 components of the Predicate Device (K970264) consists of 1) a Guiding Sheath with posterior, anterior or multipurpose shaped distal tip section, 2) a conventional sheath vessel dilator (*vessel dilator*) , 3) a dual-tapered long vessel dilator (*exchange dilator*), 4) a .032", 260cm guidewire, and 5) a guidewire funnel. The components of the Predicate Device are packaged in four configurations: 1) Guiding Sheath w/ posterior curve and vessel dilator, 2) Guiding Sheath w/ anterior curve and vessel dilator, 3) Guiding Sheath w/ multipurpose curve, vessel dilator, exchange dilator, .032", 260cm guidewire and guidewire funnel, and 4) Posterior, Anterior and Multipurpose Guiding Sheaths, vessel dilator, exchange dilator, .032", 260cm guidewire and guidewire funnel.

The packaging configuration of the Predicate Device has been modified to offer the Guiding Sheath and Exchange System in two separate packages. The Guiding Sheath (*PREFACE Braided Guiding Sheath*) with posterior, anterior or multipurpose shaped distal tip sections is packaged with a vessel dilator and a short .032", 150cm guidewire. The Exchange System includes the exchange dilator (*PERRY Exchange Dilator*), .032", 260cm guidewire, and guidewire funnel. The distal end of the vessel dilator and both ends of the PERRY Exchange Dilator were modified by adding radiopaque tips with tungsten to improve visibility under fluoroscopy. The function and intended use of the Modified Device as compared to the Predicate Device are identical, as are all component materials with the exception of the tungsten dilator material. The addition of the tungsten material does not affect safety or effectiveness as demonstrated in the Verification Test Data provided in Appendix I.

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

Device Description - Continued	The PREFACE Braided Guiding Sheaths are intended to provide stability and directional control during catheter ablation. The PREFACE Braided Guiding Sheath is packaged with a vessel dilator with a radiopaque distal tip, and a .032", 150cm guidewire. The PERRY Exchange Dilator will be utilized by the physician to exchange the existing PREFACE Braided Guiding Sheath for an alternate PREFACE Braided Guiding Sheath without losing the established intracardiac position. The PERRY Exchange Dilator with radiopaque ends is packaged with a .032", 260cm guidewire and guidewire funnel.
Intended use	The intended use of the Modified Device is to provide stability and directional control during transcatheter ablation of endocardial tissue.
Indications statement	PREFACE Braided Guiding Sheath - The intended use of the percutaneous Braided Guiding Sheath is for the introduction of intravascular electrophysiology catheters into any cardiac chamber. PERRY Exchange Dilator - The intended use of the PERRY Exchange Dilator is for the transseptal exchange of Cordis Webster PREFACE Braided Guiding Sheaths which are used for the introduction of intravascular electrophysiology catheters. The exchange dilator permits exchange of the guiding sheaths while maintaining transseptal left heart access and control of sheath location.
Technological characteristics	The technological characteristics of the Modified Device are the same as the Predicate Device.

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

Performance data	Verification testing of the Modified Device was conducted to compare the stiffness and the insertion force of the PERRY Exchange Dilator with radiopaque tip and the dilator (of the PREFACE Braided Guiding Sheath) with the standard 8F AVANTI Sheath (K970392).
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	August 5, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 1998

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

Re: K982740
Cordis Webster PREFACE Braided Guiding Sheath and
PERRY Exchange Dilator
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: August 5, 1998
Received: August 6, 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

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

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 982740

Device Name: PREFACE Braided Guiding Sheath and PERRY Exchange Dilator

Indications for Use: The PREFACE Braided Guiding Sheath is intended for the introduction of intravascular electrophysiology catheters into any cardiac chamber.

Indications for Use: The intended use of the PERRY Exchange Dilator is for the transseptal exchange of Cordis Webster PREFACE Braided Guiding Sheaths which are used for the introduction of intravascular electrophysiology catheters. The exchange dilator permits exchange of the guiding sheaths while maintaining transseptal left heart access and control of sheath location.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982740

Prescription Use ✓
(Per 21 CFR 801.109)