K021591

MAY 22 2002

0-000025

Attachment 4

Summary of Safety and Effectiveness

Submitter's Name/Contact Person

The submitter of this special 510(k) is:

Cordis Neurovascular, Inc.
14000 N.W. 57th Court
Miami Lakes, Florida 33014

Establishment Registration No. 1058196

Contact: Maritza Celaya
Sr. Regulatory Affairs Associate

Tel: (786) 313-6546
Fax: (786) 313-6480

May 14, 2002

Trade Name / Common Name

Trade Name: PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters with and without pre-shaped tips

Common/Classification Name: Catheters, Continuous Flush

Classification

Class II

Performance Standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use and Device Description

The PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters with and without pre-shaped tips are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

Device Description

The PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters with and without pre-shaped tips are a single lumen catheter featuring a stiff proximal shaft and a flexible distal section. The catheter's inner diameter accommodates guidewires of .018" and smaller for PROWLER® SELECT™ PLUS, and of 0.014" and smaller for PROWLER® SELECT™ 10 and 14, depending on the catheter type. The catheter body is radiopaque with one or two distinguishable marker(s) at the distal tip. It includes a hydrophilic coating on the outside of the shaft as well as a PTFE liner on the inner lumen.

Continued on next page

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Summary of Safety and Effectiveness, Continued 0-000026

Predicate Devices The predicate devices are listed in the table below:

Device	Company	510 (k) Number	Product Code
PROWLER® Infusion Catheters	Cordis Neurovascular, Inc.	K965181 K972518	74KRA
PROWLER® PLUS Infusion Catheters	Cordis Neurovascular, Inc.	K993266	74KRA
PROWLER® Infusion Catheters with pre-shaped tips	Cordis Neurovascular, Inc.	K003925	74KRA
PROWLER® SELECT™ 10 and 14 Infusion Catheters with and without pre-shaped tips	Cordis Neurovascular, Inc.	K020680 / 3/27/02	74KRA

Summary of Studies

Design verification testing demonstrated that the PROWLER® SELECT™ PLUS Infusion Catheters with and without pre-shaped tips performed as intended. No new questions of safety and effectiveness were raised. Design verification testing included:

- Outer Diameter Dimension Inspection (pre-coating)
- Visual Inspection
- Flexible Coil Length Inspection/Distal Zone Length Inspection
- Lateral Stiffness
- Trackability
- Joint Pull Test
- Static Burst Testing

All materials used in the PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters with and without pre-shaped tips are biocompatible.

Summary of Substantial Equivalence

The PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters with and without pre-shaped tips are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Ms. Maritza Celaya
Cordis Neurovascular, Inc.
14000 N.W. 57th Court
Miami Lakes, FL 33014

Re: K021591
PROWLER® SELECT™ PLUS Infusion Catheters with and without pre-shaped tips
Regulation Number: 870.1210
Regulation Name: Continous Flush Catheter
Regulatory Class: Class II (two)
Product Code: 74 KRA
Dated: May 14, 2002
Received: May 15, 2002

Dear Ms. Celaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021591

Device Name: PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters (with and without pre-shaped tips)

Indications for Use Statement

The PROWLER® SELECT™ (10, 14 and PLUS) Infusion Catheters are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K021591