APR 1 8 2005

K043538

510(k) Summary of Safety and Effectiveness

Applicant's Name

Cordis Neurovascular, Inc.
14000 NW 57th Court
Miami, Florida 33014

Contact Person

Maritza Celaya
Regulatory Affaris Manager
(786) 313-6546
(786) 313-6480 (Fax)

Trade Name / Common Name

The trade name of the device is: HYPERTRANSIT™ Infusion Catheter.
The common name of the device is: Catheter, Continuous Flush.

Classification

These devices have been classified as Class II, per 21 CFR 870.1210 (KRA), which have been classified within the Division of Cardiology and Respiratory Devices.

Performance Standard

There are no performance standards applicable under Section 514 of the Food, Drug and Cosmetic Act for Continuous Flush Catheters.

Intended Use

The HYPERTRANSIT™ Infusion Catheter is intended to be used as a mechanism for the infusion of various diagnostic and embolic agents in the coronary, neuro and peripheral vasculatures, for guidewire exchange/support, and for superselective angiography of the peripheral and coronary vessels. The device is also intended to be used for infusion of therapeutic agents in the coronary and peripheral vasculature.

All agents must be used in accordance with manufacturer's instructions for use

Device Description

The Cordis Neurovascular, Inc. HYPERTRANSIT Infusion Catheter is a variable stiffness, single lumen catheter designed to access small, tortuous vasculature. Each configuration has a hydrophilic coating to provide lubricity for navigation of vessels. The inner lumen is lined with PTFE to facilitate movement of guidewires and other devices. The catheter body is radiopaque to aid visualization under fluoroscopy, and the distal tip is distinguished by a radiopaque marker. Select configurations are available with pre-shaped tips.

510(k) Summary of Safety and Effectiveness, continued

Predicate Devices

The predicate devices are listed in the table below:

Device	Company	510(k) Number	Product Code	Predicate for:
MASSTRANSIT® Infusion Catheter	Cordis Neurovascular, Inc.	K983003	KRA	Intended Use Sterilization
Renegade *HI-FLO* Microcatheter	Boston Scientific Corporation	K000177	KRA	Intended Use Dimensions Performance
PROWLER® SELECT™ Infusion Catheters	Cordis Neurovascular, Inc.	K021591	KRA	Intended Use Sterilization Packaging

Summary of Studies

The following in-vitro and in-vivo testing was conducted to support substantial equivalence to the predicate devices.

Comparative Testing
Linear Stiffness
Flow Rate Testing
Shape Retention
Acute Animal Studies
Embolic Particle (PVA) Functional Compatibility Testing
Pushable Coil Functional Compatibility Testing

The following in-vitro and in-vivo testing was conducted to demonstrate the safety and effectiveness of the device, and to demonstrate that the device performs as it is intended.

Performance Testing
Dimensional Inspection
Joint Pull Test
Static Burst Test
Dynamic Burst Test
Particulate Testing
Coating Integrity
Flow Rate Testing
Acute Animal Studies
Biocompatibility Testing

Summary of Substantial Equivalence

The HYPERTRANSIT™ Infusion Catheter is similar in its basic design, indication for use, sterilization, and performance characteristics to the predicate devices, the MASSTRANSIT® Infusion Catheter, the PROWLER® SELECT™ Infusion Catheter and the Renegade *HI FLO* Microcatheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2005

Ms. Maritza Celaya
Regulatory Affairs Manager
Cordis Neurovascular, Inc.
P.O. Box 025700
Miami, FL 33102-5700

Re: K043538
Trade/Device Name: HYPERTRANSIT™ Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II
Product Code: KRA
Dated: March 18, 2005
Received: March 21, 2005

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Donna R. Vechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Cordis
a Johnson & Johnson company

Page 1 of 1

510(k) Number (if known): K043538

Device Name: HYPERTRANSIT™ Infusion Catheter

Indications for Use Statement

The HYPERTRANSIT™ Infusion Catheter is intended to be used as a mechanism for the infusion of various diagnostic and embolic agents in the coronary, neuro and peripheral vasculatures, for guidewire exchange/support, and for superselective angiography of the peripheral and coronary vessels. The device is also intended to be used for infusion of therapeutic agents in the coronary and peripheral vasculature.

All agents must be used in accordance with manufacturer's instructions for use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachmeier

(Division Sign-Off)
Division of Cardiovascular Devices

Prescription Use ✓ OR Over-The-Counter Use _____

510(k) Number K043538