SEP 23 1999

K991646
0-000032

510(k) Summary of Safety and Effectiveness

Submitter's Name/Contact Person	Alina Caraballo Regulatory Affairs Manager Cordis Endovascular Systems 14000 NW 57 Court Miami Lakes, FL 33014 Tel: (305) 512-6518
Trade Name	The trade name is : • AGILITY™ Steerable Guidewires.
Classification	This is a Class II Device.
Performance Standard	The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this device.
Device Description	The hydrophilically coated AGILITY Steerable Guidewires consist of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip. Guidewire length, diameter, and distal tip configuration are indicated on the product label. A steering/torquing device and a guidewire introducer are packaged with the AGILITY Guidewire.
Intended Use	The Cordis AGILITY™ Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

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

Device	Company	Product Code	Predicate for:
Dasher® – 10	Target Therapeutics	DQX	• Intended use • Sterilization method • Design • Corewire and coil material • Performance
TRANSEND™ Guidewire	Target Therapeutics (BSC)	DQX	• Hydrophilic coating
INSTINCT™ Guidewire	Cordis Corporation	DQX	• Intended Use • Sterilization • Packaging
ESSENCE™ Guidewire	Cordis Endovascular Systems, Inc. (CES)	DQX	• Intended Use • Sterilization • Manufacturing

Summary of Studies

In-vitro testing showed that the Agility Guidewire performs as well or better than the predicate devices tested. No new questions of safety and effectiveness were raised. Comparative testing included:

- Tensile Test
- Torque Strength
- Torque Response
- Tip Flexibility
- Lubricity Testing
- Kink Resistance

Animal study testing indicated that the device works as intended.

All appropriate biocompatibility tests were successfully performed on the materials used to manufacture the AGILITY™ Guidewire.

Summary of Substantial Equivalence

The AGILITY™ Steerable Guidewire is similar in its basic design, construction, indication for use, and performance characteristics to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Ms. Alina Caraballo
Manager, Regulatory Affairs
Cordis Endovascular Systems
P.O. Box 025700
Miami, FL 33102-5700

Re: K991646
Trade Name: AGILITY™ Steerable Guidewires
Regulatory Class: II
Product Code: DQX
Dated: September 13, 1999
Received: September 14, 1999

Dear Ms. Caraballo:

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) 594-4586. 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

510(k) Number: K991646

Indications for Use Statement

The Cordis Endovascular AGILITY™ Steerable Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

for

Division Sign-Off)
[illegible]ivision of Cardiovascular, Respiratory,
[illegible] Devices
[illegible]K) Number K991646