

K972110

**Section 513(j) of the Federal Food, Drug and Cosmetic Act  
Summary of Safety and Effectiveness**

AUG 14 1997

06/03/97

**I. General Provisions**

Common or Usual name: Infusion Catheter  
Proprietary name: Cordis Endeavor Infusion Catheter  
Name and Address of Applicant: Cordis Corporation  
Miami Lakes Operation Center  
14201 NW 60 Avenue  
Miami Lakes, FL 33014

**II. Name of Predicate Devices**

Cordis Infusion Catheters (3.0 - 3.5 mm)  
SciMed Dispatch Gold Infusion Catheters<sup>1</sup>

**III. Classification**

Infusion catheters are class II devices according to 21 CFR 870.1210.

**IV. Performance Standards**

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

**V. Intended Use and Device Description**

The Endeavor Infusion Catheter is intended to deliver solutions to the coronary and peripheral vasculature. The device is an over-the-wire design with a distal infusion region and a proximal hub. The infusion region is indicated by a central radiopaque marker band.

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<sup>1</sup> A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA has stated, "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42, 520 et seq. (1977).

## **VI. Biocompatibility**

All appropriate biocompatibility testing was performed, and successfully passed, on the materials used for the Endeavor Infusion Catheter.

## **VII. In vitro Testing**

A series of *in vitro* tests were performed to assure that the introduction of the two new sizes of Endeavor Infusion Catheter does not raise new issues of safety and effectiveness. All test results met or exceeded established specifications.

## **VIII. Summary of Substantial Equivalence**

The Endeavor Infusion Catheter is designed for the infusion of solutions to the coronary and peripheral vasculature. The Endeavor Infusion Catheters have similar intended uses, design characteristics and dimensions as the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

AUG 14 1997

Mr. Ariel MacTavish  
Regulatory and Clinical Affairs Associate  
Cordis Corporation  
14201 N.W. 60<sup>th</sup> Avenue  
Miami Lakes, Florida 33014

Re: K972110  
Endeavor Infusion Catheter  
Regulatory Class: II (two)  
Product Code: 74 KRA  
Dated: June 4, 1997  
Received: June 5, 1997

Dear Mr. MacTavish:

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 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 Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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

Enclosure

**Statement of Intended Use  
Cordis Endeavor Infusion Catheter**

The intended use statement of this product is:

The Cordis Endeavor Infusion Catheter is intended to deliver solutions, such as heparinized saline, and thrombolytic agents, such as urokinase, to the coronary and peripheral vasculature.

510(k) number           K972110            
(To be assigned by FDA)

          T.A. Re            
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number           K972110