00-00034

K970854

SEP 30 1997

PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Infiniti® Angiographic Catheters
Modification

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Angiographic Catheter
Proprietary Name: Cordis 5 F Infiniti® Angiographic Catheter
Cordis 6 F Infiniti® Angiographic Catheter

II. Name of Predicate Devices

4 F Infiniti® Angiographic Catheter, K960975, April 02, 1996
6 F Paragon (Infiniti®) Angiographic Catheter, K921310/A, Sept. 17, 1992

III. Classification

Class II

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 Cordis 5 F and 6 F Infiniti® Angiographic Catheters are indicated for the delivery of radiopaque contrast medium to selected sites in the vascular system.

The catheters included in this submission are 5 F and 6 F in diameter with a braided proximal shaft and a variety of tip configurations.

VI. Biocompatibility

All appropriate biocompatibility tests were previously performed on the materials used for the 5 F and 6 F Infiniti® Angiographic Catheters. No new tests were performed, since all materials had been successfully tested on previously concurred devices.

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VII. Summary of Substantial Equivalence

The Cordis 5 F and 6 F Infiniti® Angiographic Catheters are similar in design, construction, indication for use, and performance characteristics to other commercially angiographic catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Elena S. Jugo, M.D.
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102-5700

SEP 30 1997

Re: K970854
5 Fr and 6 Fr Infiniti® Angiographic Catheters
Regulatory Class: II (two)
Product Code: DQO
Dated: July 2, 1997
Received: July 3, 1997

Dear Dr. Jugo:

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 (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) 594-4648. 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

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

00-0053

PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Infiniti® Angiographic Catheters
Modification

510(k) Number (if known): K970854

Device Name: 5 F and 6 F Infiniti® Angiographic Catheters

Indications for Use:

Cordis Angiographic Catheters are designed to deliver radiopaque contrast medium to selected sites in the vascular system.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)