OCT 8 1999

K992347

510(k)

Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis Super Torque MB Angiographic Catheter with Radiopaque Marker Bands	Angiographic Catheter with Marker Bands

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis 5.2 F Super Torque Plus Angiographic Catheter
- Cook Aurous™ Graduated Sizing Catheter
- Guidant EVT AngioScale Angiographic Catheter

Classification

Class II.

Performance Standards

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

Indications for Use

The Super Torque MB Angiographic Catheter with radiopaque marker bands is intended to provide angiographic visualization and linear measurements of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

Device Description

The Cordis Super Torque MB Angiographic Catheter with radiopaque marker bands consists of a 5.0 F single lumen, braided catheter having a minimum of two and maximum of twenty radiopaque, gold-alloy, marker bands circumferentially mounted on the a non-braided catheter tip.

The Super Torque MB Angiographic Cathete with radiopaque marker bands will be offered in catheter lengths ranging from 65 cm to 125 cm.

Biocompatibility

All materials used in the Cordis Super Torque MB Angiographic Catheter with radiopaque marker bands are biocompatible.

Summary of Substantial Equivalence

The Cordis Super Torque MB Angiographic Catheter with Radiopaque Marker Bands is substantially equivalent to the predicate devices. The equivalence was confirmed through non-clinical tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

Ms. Karen Wilk
Senior Regulatory Affairs Associate
Cordis Corporation
P.O. Box 4917
Warren, NJ 07059

Re: K992347
Trade Name: Cordis Super Torque MB Angiographic Catheter with Radiopaque Marker Bands
Regulatory Class: II
Product Code: DQO
Dated: July 13, 1999
Received: July 14, 1999

Dear Ms. Wilk:

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: K992347

Device Name: Cordis Super Torque MB Angiographic Catheter with Radiopaque Marker Bands

Indications for Use: The Cordis Super Torque MB Angiographic Catheter with Radiopaque Marker Bands is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

(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

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number K992347