JUN 25 1999

00-00021

K990771

Attachment 1

Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis 6F Hydrolyser Thrombectomy Catheter	Embolectomy Catheter

Name of Predicate Device

The device is substantially equivalent to:

- Cordis 7F Hydrolyser Thrombectomy 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 6F Hydrolyser is indicated to percutaneously remove soft, newly formed (≤ 5 days old) thrombus from dialysis shunts.

Device Description

The Cordis 6F Hydrolyser Thrombectomy Catheter system consists of a 6F Catheter and an Accessory Kit.

The 6F Catheter is a 65 cm triple lumen catheter which consists of an injection lumen that allows for saline to be injected, an exhaust lumen that allows for the fluid to be transported into a collection bag and a guidewire lumen.

Biocompatibility

All materials used in the Cordis 6F Hydrolyser Thrombectomy Catheter are biocompatible.

Summary of Substantial Equivalence

The Cordis 6F Hydrolyser Thrombectomy Catheter is substantially equivalent to the predicate device. The equivalence was confirmed through pre-clinical and clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

Ms. Ariel MacTavish
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K990771
6F Hydrolyser Thrombectomy Catheter
Regulatory Class: II (two)
Product Code: 74 DXE
Dated: June 9, 1999
Received: June 10, 1999

Dear Ms. 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 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) 594-4648. 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/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

00-00051

Attachment 3

Indications for Use Statement

510(k) Number (if known)	K990771
Device Name	Cordis 6F Hydrolyser Thrombectomy Catheter
Indications for Use	The 6F Hydrolyser is indicated to percutaneously remove soft, newly formed (≤ 5 days old) thrombus from dialysis shunts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K990771

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)