K981407

Attachment 4

MAY 20 1998

Summary of Safety and Effectiveness

General Provisions

Trade Name: Opta LP PTA Balloon Catheter
Powerflex Plus PTA Balloon Catheter

Common/Classification Name: Peripheral Transluminal Angioplasty Balloon Catheter

Name of Predicate Devices

Cordis Opta LP PTA Balloon Catheter
Cordis Powerflex Plus PTA Balloon Catheter
Cordis Opta5 PTA Balloon Catheter
Cordis Powerflex PTA Balloon 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.

Intended Use and Device Description

The Opta LP and Powerflex Plus PTA Balloon Catheters are intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and, for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Opta LP and Powerflex Plus PTA Balloon Catheters have a dual lumen design with distal inflatable balloon. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement.

All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure.

The balloon inflation lumen is used to inflate and deflate the balloon. The nominal balloon size is printed on the hub.

The guidewire lumen is used to track the catheter over a prepositioned guidewire or to inject contrast medium and/or saline. The maximum injection pressure is 150 psi. The compatible guidewire size, catheter shaft French size and catheter length are printed on the hub. The radiopaque marker bands indicate the stated nominal length of the balloon

Biocompatibility

All materials used in the Opta LP and Powerflex Plus PTA Balloon Catheters are biocompatible.

Summary of Substantial Equivalence

The Opta LP and Powerflex Plus PTA Balloon Catheters described in this submission are similar in their basic design, construction, indications for use and performance characteristics to Opta LP, Powerflex Plus, Opta5 and Powerflex PTA catheters which previously received 510(k) concurrence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Mirjam Barboza, M.D.
Manager, Regulatory Affairs
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K981407
Trade Name: Cordis Opta LP PTA Balloon Catheter and Cordis Powerflex Plus PTA Balloon Catheter
Regulatory Class: II
Product Code: LIT
Dated: April 17, 1998
Received: April 20, 1998

Dear Dr. Barboza:

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) 594-4692. 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

Indications for Use Statement

510(k) Number (if known)

Device Name Cordis Powerflex Plus PTA Balloon Catheter

Indications for Use The Powerflex Plus PTA Balloon Catheter is indicated to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries, and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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 K981407

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____