K032737

OCT - 2 2003

Attachment 1

Summary of Safety and Effectiveness

Submitter & Contact person:

Cordis Europa, N.V.,
a Johnson & Johnson Company
Oosteinde 8
NL-9300 LJ Roden,
The Netherlands

Harm Hovinga
Senior Regulatory Affairs Associate
Tel (+31) (5050) 22479
Fax: (+31) (5050)-22456
e-mail: hhovinga@crdnl.jnj.com

Date Prepared *October 1, 2003*

Trade Name

Cordis PowerFlex™ Extreme PTA Balloon Catheter
Cordis PowerFlex™ P3 PTA Balloon Catheter
Cordis OPTA™ PRO PTA Balloon Catheter

Classification Name & Device Classification

Common Name: Peripheral Transluminal Angioplasty Balloon Catheter.
Classification Name: 21 CFR 870.1250: Percutaneous Catheter.
Class II; Product Code: #74LIT.

Device description

The modified PTA catheters described in this submission are virtually identical to its original cleared devices, which received 510(k) concurrence.

The Cordis over-the-wire (OTW) PTA balloon catheters have a dual lumen design with a distal inflatable balloon. Two radiopaque marker bands indicate the dilatation section of the balloon and aid in balloon placement. The radiopaque marker bands indicate the nominal length of the balloon. The balloon inflation lumen is used to inflate and deflate the balloon. The guide wire lumen is used to track the catheter over a pre-positioned guide wire or to inject contrast medium and/or saline.

Compared to the previously cleared predicate devices, the devices in this submission are identical, except for the following feature:

- Polyamide hub instead of polycarbonate hub
- Injection molded hub instead of UV-glued hub
- Slight design configuration change for user preference.

Name of affected devices

Cordis PowerFlex™ Extreme PTA Balloon Catheter
Cordis PowerFlex™ P3 PTA Balloon Catheter
Cordis OPTA™ PRO PTA Balloon Catheter

Performance standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards for these devices.

Conclusion

The Cordis PowerFlex Extreme, PowerFlex P3 and Opta Pro PTA balloon catheters are substantially equivalent to the predicate devices.

Intended Use

The **POWERFLEX EXTREME** PTA catheter is intended for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries.

The **POWERFLEX P3** PTA catheter is 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 PRO** PTA catheter is 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.

Safety and Performance Data

The safety and effectiveness of the affected PTA Balloon Catheters have been demonstrated via data collected from non-clinical design verification tests and analyses. All materials used in these modified devices have been tested according to ISO 10993-Part 1 and were found biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Cordis Corporation
c/o Ms. Karen Wilk
Manager, Regulatory Affairs
7 Powder Horn Drive
Warren, NJ 07059

Re: K032737
Trade/Device Name: Cordis PowerFlex Extreme, PowerFlex P3, and OPTA PRO Percutaneous Transluminal Balloon Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 3, 2003
Received: September 4, 2003

Dear Ms. Wilk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510 (k) Number: _____

Device Names: **The Cordis POWERFLEX™ EXTREME Percutaneous Transluminal Angioplasty (PTA) Catheter, the POWERFLEX™ P3 PTA Catheter and the OPTA™ PRO PTA Catheter**

Indications For Use:

The **POWERFLEX EXTREME** PTA catheter is intended for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries.

The **POWERFLEX P3** PTA catheter is 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 PRO** PTA catheter is 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.

(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 Cardiovascular, Respiratory and Neurological Devices

510(k) Number K032737

Special 510 (k) Number: _____