K121442

JUN 14 2012

Cordis®
a Johnson & Johnson company

510(k) Summary

Submitter: Cordis Corporation, a Johnson & Johnson company
430 Route 22 East
Bridgewater, NJ 08807

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Date Prepared: May 14, 2012

Device Trade Name: Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter

Device Common Name: Peripheral Transluminal Angioplasty Balloon Catheter

Class: II

Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Product Code: LIT

Predicate Devices:

Device	Company	Product Code	510(k) Number	Predicate for: (if multiple predicates)
Powerflex™ PRO PTA Catheters	Cordis Corporation	LIT	K112797	Design, Materials, Construction, Characteristics

Device Description:

The Powerflex™ Pro Percutaneous Transluminal Angioplasty (PTA) catheter is a catheter with a distal inflatable balloon. The Powerflex™ Pro PTA Catheter is designed for use with a 0.035" guide wire and a catheter sheath introducer and is available in a variety of diameters and lengths. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses.

Indications for Use:

The Powerflex™ Pro Percutaneous Transluminal Angioplasty (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 device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Summary of Performance Testing:

The safety and effectiveness of the Powerflex™ Pro PTA Catheter and the substantial equivalence to the predicate devices have been demonstrated via data collected in non-clinical design verification. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. All materials used in the proposed device are the same to the predicate device and meet the requirements of ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process.

The following in-vitro performance tests were completed for the Powerflex™ Pro PTA Catheter:

Marker Band Spacing
Balloon Diameter (Nominal, RBP)
System Burst (Inflation Lumen)
System Burst (Guide wire Lumen)
Hub to Shaft Pull Strength
CSI Insertion
Kink Diameter Catheter Shaft
Inflation/Deflation Time
Multiple Inflation (System Fatigue)
Torque Testing
Particle Free
Hemolysis
Balloon Working Length
Balloon Burst
Marker Band Placement
Proximal Pull Strength
Tip to Balloon/Inner Body Pull Strength
CSI Withdrawal Force
Guide Wire Compatibility
Useable Catheter Length
Rated Burst Pressure
PreConditioning Tensile Testing
Cytotoxicity
Physicochemical Aqueous Extraction

Summary of Substantial Equivalence Comparison:

The subject Powerflex Pro PTA Catheter is identical to the predicate Powerflex Pro PTA Catheter described in 510(k) #K112797, with the exception of additional length/diameter combinations within the existing ranges of length and diameter. The subject device has the same fundamental scientific technology and intended use as the current, legally marketed Powerflex™ Pro PTA Catheter. The subject and predicate devices share the same materials, design, fundamental technology (operating principle), labeling, packaging materials and configuration, shelf life and sterilization process. The additional sizes meet the same requirements as the current FDA cleared [510(k) K112797] devices.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing, the additional sizes of Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Cordis Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter (K112797).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2012

Cordis Corporation
c/o Donna Marshall
430 Route 22 East
Bridgewater, NJ 08807

Re: K121442
Trade/Device Name: Powerflex™ Pro Percutaneous Transluminal Angioplasty (PTA) Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: May 14, 2012
Received: May 15, 2012

Dear Ms. Marshall:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K121442

Device Name:

Powerflex™ Pro Percutaneous Transluminal Angioplasty Catheter

Indications for Use:

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Prescription Use __X__ OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Devices

510(k) Number K121442