K101651

510(k) Summary

Applicant

Cordis Corporation, a Johnson & Johnson Company
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Bridgewater, New Jersey 08807
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JUL - 9 2010

Contact Person

Joan Martin
Manager
Regulatory Affairs

Date

June 10, 2009

Device Name

Trade Name:	ANGIOGUARD™ XP Emboli Capture Guidewire ANGIOGUARD™ RX Emboli Capture Guidewire
Common or Usual Name:	Common Name: Embolic Protection Guidewire Cardiovascular Percutaneous Catheter per 21 CFR 870.1250 and Catheter Guidewire per 21 CFR 870.1330
Classification:	Class II
Classification Panel	Cardiovascular

Predicate Devices

The device is substantially equivalent to Cordis' current, legally-marketed ANGIOGUARD™ XP Emboli Capture Guidewire and ANGIOGUARD™ RX Emboli Capture Guidewire which were found to be substantially equivalent to Boston Scientific's FilterWire EX Embolic Protection System (K023691) and PercuSurge, Inc.'s Percusurge Guardwire Temporary Occlusion and Aspiration System (K013913) via 510(k) K062531 on September 22, 2006.

Device Description

Both subject and predicate ANGIOGUARD XP and RX devices consist of a guidewire with integrated emboli filter basket at the distal end. The devices function as an interventional guidewire and distal protection device during delivery and placement of stents and interventional devices in carotid procedures. The guidewire is delivered via an OTW (over-the-wire) or RX (rapid-exchange) deployment sheath and is captured via an OTW or RX capture sheath. ANGIOGUARD devices have a filter basket at the distal end that is deployed prior to the stenting procedure. When deployed, the filter basket opens in an umbrella-like fashion, allowing passive hemo-filtration with subsequent emboli capture. At the end of the procedure, the filter is collapsed and retrieved.

Intended Use

The subject and predicate ANGIOGUARD XP and ANGIOGUARD RX Emboli Capture Guidewire devicves are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5 mm.

Summary of Substantial Equivalence

With the exception of a change to the adhesive material used to adhere radiopaque markers to the filter basket struts, the subject and predicate devices share the same:

- Intended use
- Indication for use
- Design & Dimensions
- Size Range
- Materials (with exception of adhesive material change described herein)
- Fundamental technology and operating principle
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Labeling / Instructions for use
- Shelf Life

The subject ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices are substantially equivalent to the predicate ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices.

Summary of & Conclusions Drawn from Design Verification Activities

Design verification activities (Deployment and Capture Testing, Visual Inspections, Bioburden, Endotoxin, EtO residual testing and biocompatibility testing per ISO 10993-1) were conducted to confirm that the modified devices meet the same requirements as the current, legally marketed predicate devices.

Results demonstrated that design outputs continue to meet device inputs. Hence, the subject ANGIOGUARD XP and RX Emboli Capture Guidewire devices are substantially equivalent to the current, legally marketed ANGIOGUARD XP and RX Emboli Capture Guidewire predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL - 9 2010

Cordis Corporation
c/o Joan Martin
Manager, Regulatory Affairs
430 Route 22 East
Bridgewater, NJ 08807

Re: K101651
Trade/Device Name: Angioguard XP and RX Emboli Capture Guidewires
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NTE
Dated: June 10, 2010
Received: June 11, 2010

Dear Ms. Martin:

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,

Donna R. Vickers

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

Enclosure

Indication for Use

510(k) Number: K101651

Device Name: ANGIOGUARD™ XP Emboli Capture Guidewire System

Indications For Use: The ANGIOGUARD™ XP Emboli Capture Guidewire is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5 mm.

Prescription Use: _X_ AND/OR Over-The-Counter Use: ____
(Part 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 K101651

Indication for Use

510(k) Number: K101651

Device Name: ANGIOGUARD™ RX Emboli Capture Guidewire System

Indications For Use: The ANGIOGUARD™ RX Emboli Capture Guidewire is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5 mm.

Prescription Use: X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: ____ (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)

Donna R. VanAmen

(Division Sign-Off)
Division of Cardiovascular Devices

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