JUN 27 2014

Cordis

SECTION 5.
510(k) SUMMARY

(As Required By 21 CFR 807.92(a))

A. Company Information

Company Name:	Cordis Corporation (Manufacturer)
Address:	6500 Paseo Padre Parkway Fremont, CA 94555
Contact Person:	Kim Fonda
Telephone:	(510) 248-2480
Fax:	(510) 248-2533
Date of Submission:	Dec. 16, 2013
Company Name:	Cordis Cashel (Legal Manufacturer)
Address:	Cahir Road Cashel Co. Tipperary, Ireland
Contact Person:	Kim Fonda
Telephone:	(510) 248-2480
Fax:	(510) 248-2533

B. Trade/Device Name: SABER™ Percutaneous Transluminal Angioplasty Dilatation Catheter

Common Name: Percutaneous Catheter

Classification Name: Catheter, angioplasty, peripheral, transluminal

Regulation Number: 21 CFR 870.1250 – Percutaneous Catheter

Product Code: LIT

C. Predicate Device Information:

Predicate Devices			
510(k) Number	**Date Cleared**	**Device Name**	**Manufacturer**
K971010	6/18/1997	SAVVY® PTA Balloon Catheter	Cordis Corp.

K121442	6/14/2012	Powerflex® Pro Percutaneous Transluminal Angioplasty Balloon Catheter	Cordis Corp.
K103464	12/22/2010	Invatec Pacific™ Xtreme PTA Balloon Catheter	Medtronic Inc

D. Device Description:

The SABER™ PTA Catheter is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter consisting of a proximal hub and distal dilatation balloon, connected by a coaxial, concentric dual lumen shaft. Radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. A hydrophilic coating covers the distal tip, balloon, and sections of the shaft, to facilitate balloon placement.The SABER™ PTA Catheter is compatible with 4F, 5F, and 6F catheter introducer sheaths, and with guidewires having a maximum diameter of 0.018 inches. The SABER™ PTA Catheter is available in a variety of sizes, ranging from 2 to 10 mm in diameter and 20 to 300 mm in length, and useable length of either 90 or 150 cm. It is packaged as a single use, sterile device.

E. Intended Use:

The SABER™ 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-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

F. Summary of technological characteristics of the proposed device to the predicate devices:

The SABER™ PTA Catheter has the following similarities to the predicate devices:

- Same intended use
- Same operating principle
- Method of delivery
- Components
- Performance properties
- Device dimensions
- Device labeling
- Manufacturing processes
- Same sterilization methods and sterility assurance level

- Packaging materials and configurations

The intended use of the SABER™ PTA Catheter is identical to the predicate Powerflex® Pro PTA Catheter. The differences between the SABER™ PTA Catheter and predicate devices do not raise any new questions of safety and effectiveness.

Summary of Nonclinical Testing:
Bench, animal and biocompatibility testing were performed to support a determination of substantial equivalence. Results of testing demonstrated that the SABER™ PTA Catheter has been tested to assure conformance to the requirements for its intended use.

The SABER™ PTA Catheter is an externally communicating device, contacting circulating blood for < 24 hours. Appropriate testing was determined in accordance with Cordis Risk Analysis procedures. All tests recommended in ISO 10555-1, *Intravascular catheters- Sterile and single-use catheters - Part 1: General Requirements (July 2013,)* and 10555-4, *Intravascular catheters- Sterile and single-use catheters - Part 4: Balloon dilatation catheters (June, 2013)*, have been performed. Biocompatibility tests were performed in accordance with *Biological evaluation of medical devices - Part 1: Evaluation and testing.*

The following tests were performed:

SABER™ PTA Catheter testing	
Performance	**Biocompatibility**

• Dimensional Verification
  ○ Useable catheter length
  ○ Marker band spacing
  ○ Marker band placement
  ○ Balloon working length
• Visual inspection
• Catheter sheath introducer withdrawal
• Guidewire compatibility
• Preparation verification
• Kink diameter
• Balloon deflation time
• Balloon inflation time
• Proximal seal tensile test
• Hub to shaft tensile test
• Tip to balloon tensile test
• Minimum burst strength, shaft
• Balloon Burst
• Balloon diameter compliance at nominal inflation
• Balloon diameter compliance at rated burst pressure inflation
• Particulate test
• Outer Surface Friction test
• System fatigue without stent
• System fatigue with stent
• Balloon burst in stent
• Torque
• Packaging : Dye leak and Seal strength
	• Cytoxicity
	• Sensitization
	• Irritation
	• Acute systemic toxicity
	• Pyrogenicity
	• Hemocompatibility: hemolysis
	• Hemocompatibility: partial thromboplastin
	• Hemocompatibility: platelet and leukocyte counts
	• Hemocompatibility: complement activation
	• Hemocompatibility: in vivo thrombogenicity
	• Genotoxicity
	• Physiochemical tests

The SABER™ PTA Catheter was validated by three physicians in one animal study using a swine model. This testing was performed to establish by objective evidence that the Saber .018 inch PTA Catheter conforms to the user needs such as insertion and withdrawal, trackability, crossability, visibility, marker band visibility, placement, and inflation and deflation time. The Saber PTA Catheter met all predetermined acceptance criteria of design verification and validation. Testing results identified no new questions of safety or

effectiveness, and demonstrate that the technological characteristics and device performance of the SABER™ PTA Catheter are comparable to currently marketed devices.

G. Summary of Clinical Testing:

No clinical studies were deemed necessary to support substantial equivalence, as appropriate verification and validation of device requirements were achieved based on the similarities of the proposed device to the predicate device, and from results of bench and animal testing.

Conclusion:

Information contained within this submission demonstrates that the SABER™ PTA Catheter:

- Has legally marketed predicate devices
- Has identical indications for use as the predicate Powerflex® Pro PTA Catheter device
- Incorporates the same fundamental technology, and uses accepted scientific methods and international standards to evaluate device safety and effectiveness
- Demonstrates that the design and performance of the SABER™ PTA catheter has equivalent safety and performance characteristics of predicate devices, and does not raise different questions of safety and effectiveness.

Based upon the intended use, design, performance characteristics, and the non-clinical performance testing performed by Cordis Corporation, and from comparison to legally marketed devices, it is concluded that the SABER™ PTA Catheter is appropriate for its intended use, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 27, 2014

Cordis Corporation
Ms. Kim Fonda
Regulatory Affairs Project Manager
6500 Paseo Padre Parkway
Fremont, CA 94555

Re: K133843
Trade/Device Name: SABER™ Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 16, 2014
Received: May 19, 2014

Dear Ms. Fonda:

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 contact 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. 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

510(k) Number: K133843

Device Name: SABER™ Percutaneous Transluminal Angioplasty Dilatation Catheter

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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 Center for Devices and Radiological Health (CDRH)