MAY 14 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K081130

Applicant Information:

Date Prepared: April 18, 2008

Name: BridgePoint Medical
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Contact Person: Michael A. Daniel
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Facsimile Number: (925) 254-5187

Device Information:

Classification: Class II Percutaneous Catheter
Trade Name: BridgePoint Medical CrossBoss™ Catheter
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices:

The BridgePoint Medical CrossBoss Catheter is substantially equivalent in intended use, method of operation and technical aspects to a combination of the following predicate devices:

K011562 – LuMend Percutaneous Catheter
K051772 – Asahi Tornus Support Catheter
K911547 - Magnum-Meier Recanalization Guidewire

Device Description:
The CrossBoss Catheter is a single use over the wire disposable percutaneous catheter consisting of a full length coiled stainless steel shaft with polyester and polyurethane exterior. The coiled shaft provides torque and makes it possible to push the device, and also provides a guidewire lumen. The distal shaft transitions to an enlarged (1mm diameter) rounded distal tip. This stainless steel tip provides an atraumatic element that is intended to enhance the catheter's ability to move within the vasculature with reduced

risk of arterial tissue engagement while providing radiopaque visibility. The distal portion of the CrossBoss Catheter is hydrophilic coated to enhance lubricity. The proximal portion includes an internal stainless steel hypotube stiffener that provides the additional tolerance to push. A torque device, coaxially positioned over the proximal portion of the CrossBoss Catheter, provides a comfortable user interface for device manipulation. The torque device (similar to a guidewire torque device) is positionable along the proximal portion of the catheter and includes a torsion release safety mechanism. This safety mechanism insures the torque input generated by the user remains within the torsional operating strength of the catheter shaft.

Intended Use:

The BridgePoint Medical CrossBoss™ Catheter is intended to be used in conjunction with a guidewire in order to access discrete regions of the coronary or peripheral vasculature. It may be used to facilitate placement of guidewires and other interventional devices.

Comparison to Predicate Device(s):

The design of the BridgePoint Medical CrossBoss™ Catheter is similar to the predicates listed, the LuMend Percutaneous Catheter (K011562) and the Asahi Tornus Support Catheter (K051772) in that they are all devices designed to access discrete regions of the coronary and peripheral vasculature. The enlarged (1mm diameter) rounded distal tip is technically similar to the Magnum-Meier Recanalization Guidewire (K911547).

Device Evaluation Information Provided:

A variety of *in vitro* and *in vivo* information has been provided demonstrating substantial equivalence.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the BridgePoint CrossBoss Catheter has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Bridegepoint Medical
c/o Mr. Michael A. Daniel
Regulatory and Clinical Affairs
2800 Campus Drive #50
Plymouth, MN 55441

Re: K081130
BridgePoint Medical CrossBoss™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 24, 2009
Received: April 27, 2009

Dear Mr. Daniel:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: K081130

Device Name: **BridgePoint Medical CrossBoss™ Catheter**

Indications For Use:

The BridgePoint Medical CrossBoss™ Catheter is intended to be used in conjunction with a guidewire in order to access discrete regions of the coronary or peripheral vasculature. It may be used to facilitate placement of guidewires and other interventional devices

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. Johnson

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081130