AUG 2 8 2009

9. 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: K091841

Applicant Information:

Date Prepared:	May 18, 2009
Name:	BridgePoint Medical
Address:	2800 Campus Drive, #50 Plymouth, MN 55441 Phone: 763-225-8500 Fax: 763-225-8718
Contact Person:	Jill Munsinger
Phone Number:	office: 763-225-8510 / cell: 651-270-0572
E-mail:	jmunsinger@bridgepointmedical.com

Device Information:

Classification:	Class II Percutaneous Catheter
Trade Name:	CrossBoss™ Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter

Predicate Devices:

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

K081130 – CrossBoss™ Catheter

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 with revised instructions for use is identical to the original cleared CrossBoss™ Catheter (K081130) with the exception of an additional contraindication.

Summary:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Bridgepoint Medical, Inc.
c/o Ms. Jill Munsinger
Regulatory Affairs
2800 Campus Drive, #50
Plymouth, MN 55441

AUG 2 8 2009

Re: K091841
Trade/Device Name: BridgePoint Medical CrossBoss™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 6, 2009
Received: August 7, 2009

Dear Ms. Munsinger:

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

8. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA) K091841

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___ 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)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091841