MAY 1 0 2011

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: _____

Applicant Information:

Date Prepared: January 18, 2011

Name: BridgePoint Medical
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Plymouth, MN 55441
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Device Information:

Trade Name	Common Name	Classification Name	Class
CrossBoss™ Catheter	Percutaneous Catheter	Percutaneous Catheter	Class II
Stingray™ Orienting Balloon Catheter	Percutaneous Catheter	Percutaneous Catheter	Class II
Stingray™ Guidewire	Percutaneous Guidewire	Percutaneous Guidewire	Class II

Predicate Devices:

The BridgePoint Medical System (comprised of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire) is substantially equivalent (and in some cases identical) in intended use and/or method of operation and technical aspects to the following predicate devices:

Device	Reference 510(k) Number
LuMend Frontrunner™ CTO Catheter	K013284, K023223, K023114, K031005, and K033535
CrossBoss™ Catheter	K081130 and K091841
Stingray™ Orienting Balloon Catheter	K080987 and K101591
Stingray™ Guidewire	K081187 and K083727

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 additional 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.

The Stingray Orienting Balloon Catheter is a single use, over-the-wire, disposable, dual lumen percutaneous catheter that facilitates the placement, support and steering of a guidewire into discrete regions of the coronary and peripheral vasculature through the central guidewire lumen or through one of two side-ports (identified by radiopaque markers). The side-ports connect with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the catheter. The catheter contains a small non-compliant balloon segment used for fluoroscopic orientation on the distal tip of the flexible shaft.

The Stingray Guidewire is a conventionally constructed 0.014" diameter, single use, disposable guidewire that consists of a full-length stainless steel shaft with proximal PTFE coating where the distal portion of the shaft is taper ground to provide distal flexibility. The distal portion also includes a coaxially positioned coil constructed of platinum/tungsten material for visibility under fluoroscopy. The coil is fixed to the stainless steel core wire via silver alloy solder and is coated with hydrophilic coating. The distal tip of the guidewire is supplied with an angled geometry which transitions to a conventional rounded tip. The core wire (~0.0035" diameter) extends approximately 0.007" distal of the rounded tip.

Intended Use:

The BridgePoint Medical System (consisting of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire) is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions) prior to PTCA or stent intervention.

Comparison to Predicate Device(s):

The designs of the devices comprising the BridgePoint Medical System are identical to their respective predicate devices. Bench testing was previously conducted using the CrossBoss Catheter, Stingray Orienting Balloon Catheter, and Stingray Guidewire predicate devices in tests designed to address a chronic total occlusion application. Therefore, all prior bench performance testing (tensile, torque, kink resistance, trackability, corrosion, coating durability, particulate, balloon performance, dimensional, etc.) are directly applicable to this application. As well, all previous biocompatibility tests conducted for the aforementioned predicate devices is directly applicable to the devices that comprise the BridgePoint Medical System as they are identical.

As demonstrated in both animal studies and human clinical evaluations, the devices used as a system functions to enhance medical practice in facilitating the placement of guidewires or other interventional devices beyond chronic total occlusions. A 147 patient study was conducted in the United States that demonstrated the BridgePoint Medical System could successfully allow the placement of guidewires beyond chronic total occlusions with no significant increase in risk to the patient.

Summary:

Based upon the intended use and descriptive information provided in this pre-market notification, the BridgePoint Medical System consisting of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire has been shown to be substantially equivalent to the currently marketed predicate devices.

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

MAY 10 2011

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

Re: K102725/S003
Trade/Device Name: Crossboss™ Catheter Model M-2000, Stingray™ Orienting Balloon Catheter Model M-1000 & Stingray™ Guidewire Model M-3004
Regulation Number: 21 CFR 870.1250 & 870-1330
Regulation Name: Percutaneous Catheter & Catheter guide wire
Regulatory Class: Class II
Product Code: DQY & DQX
Dated: April 8, 2011
Received: April 11, 2011

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

7. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA)

Device Name: **BridgePoint Medical System consisting of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire**

Indications For Use:

The BridgePoint Medical System (consisting of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire) is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions) prior to PTCA or stent intervention.

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)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102725