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: K101591

Applicant Information:

Date Prepared: June 28, 2010

AUG 06 2010

Name: BridgePoint Medical
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Contact Person: Jill Munsinger
Phone Number: office: 763-225-8510 / cell: 651-270-0572
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Device Information:

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

Predicate Devices:

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

K080987 – Stingray™ Orienting Balloon Catheter

Device Description:

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.

Intended Use:

The BridgePoint Medical Stingray™ Orienting Balloon Catheter is indicated for directing, steering, controlling, and supporting a guide wire in order to access discrete regions of the coronary and peripheral vasculature.

Comparison to Predicate Device(s):

The design of the BridgePoint Medical Stingray™ Orienting Balloon Catheter is similar to the original cleared Stingray™ Orienting Balloon Catheter (K080987) with the exception of the balloon material durometer, manifold adhesive, and wire lumen dimension and material. The modified Stingray™ Orienting Balloon underwent the following evaluations and has demonstrated substantially equivalent performance characteristics as compared to the predicate Stingray™ Orienting Balloon:

- Tensile
- Torque
- Hub Leak
- Kink Resistance
- Guidewire Insertion/Withdrawal
- Distal Flexibility
- Distal Trackability
- Balloon Burst
- Balloon Fragmentation
- Balloon Fatigue
- Balloon Inflation/Deflation
- Balloon Dimensions
- Crossing Profile
- Guidewire Redirection
- Markerband Movement
- Markerband Removal
- Coating Coverage and Delamination
- Particulate
- Surface Defects
- Wire Insertion Through Hub
- Hemostasis Valve
- Balloon Protector Removal
- Guidewire/Markerband Interaction
- Hub Aspiration

The following design evaluations were not performed on the modified device as the device and performance characteristics of the modified device have not changed from the predicate Stingray™ Orienting Balloon Catheter:

- Radiopacity
- Corrosion Resistance
- Packaging

As well, the modified Stingray™ Orienting Balloon Catheter has undergone the following biocompatibility evaluations and has met the required specifications demonstrating the device is biocompatible:

- Cytotoxicity
- Sensitization
- Intracutaneous Injection
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Unactivated Partial Thromboplastin Time
- *In vivo* Thrombogenicity
- Complement Activation
- *In vitro* Hemocompatibility
- Physiochemical Evaluates

Summary:

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

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

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

AUG 06 2010

Re: K101591
Trade/Device Name: BridgePoint Medical Stingray™ Orienting Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Dated: July 16, 2010
Received: July 19, 2010

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

AUG 06 2010

510(k) Number (if known): K101591

Device Name: BridgePoint Medical Stingray™ Orienting Balloon Catheter

Indications For Use:

The BridgePoint Medical Stingray™ Orienting Balloon Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary and peripheral vasculature

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 K101591