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3. 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: _TBD K 080987

Applicant Information:

Date Prepared: April 5, 2008
Name: BridgePoint Medical
Address: 2800 Campus Drive, #50
Plymouth, MN 55441
Phone: 763-225-8500
Fax: 763-225-8718
Email: info@bridgepointmedical.com

Contact Person: Michael A. Daniel
Phone Number: Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number: (925) 254-5187

Device Information:

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

Predicate Devices:

The BridgePoint Medical Stingray Orienting Balloon 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
K061843 – Venture Wire Control Catheter Model WCC
K041151 – Kerberos Occluding Guide Catheter and Accessories

Device Description:
The Stingray Orienting Balloon Catheter is a single use, over the wire, disposable percutaneous catheter consisting of a distal inflatable element, that when inflated with radiopaque contrast media provides visibility and intra-arterial stability. The catheter also includes a proximal shaft that provides flexibility and push and includes a guidewire lumen. The distal inflatable element consists of two small caliber inflatable Pebax® balloons positioned adjacent to a Pebax® and PTFE guide wire lumen. When inflated, these small caliber balloons along with the guidewire lumen define a planar geometry where the width of the construction (2.5 mm) is approximately 2.5 times its height.

Within the inflatable element, the distal portion of the catheter includes two oppositely facing lateral ports that communicate with the central guide wire lumen. These ports allow the operator to direct a guidewire from the wire lumen outward at an angle (approximately 45°) to the catheter shaft. The Stingray Orienting Balloon Catheter has radiographic marks that allow the physician to determine the orientation of the catheter with respect to the vasculature. The distal portion of the Stingray Orienting Balloon Catheter is hydrophilic coated to enhance lubricity.

Intended 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.

Comparison to Predicate Device(s):
The design of the BridgePoint Medical Stingray Orienting Balloon Catheter is similar to the predicates listed, the LuMend Percutaneous Catheter (K011562) and the Venture Wire Control Catheter Model WCC (K061843) in that they are all devices designed to access discrete regions of the coronary and peripheral vasculature. The mechanism of operation, of the non-therapeutic inflatable balloon elements at the distal tip, is technically similar to the Kerberos Occluding Guide Catheter and facilitates stability, visual orientation and placement of the central guidewire.

Summary:
Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the BridgePoint Medical Stingray Orienting Balloon 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

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BridgePoint Medical
c/o Mr. Michael A. Daniel
Acting Vice President, Regulatory and Clinical Affairs
Daniel & Daniel Consulting
8 Snowberry Court
Orinda, CA 94563

Re: K080987
Trade/Device Name: Stingray™ Orienting Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 27, 2009
Received: January 29, 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 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,

Donna R. Vochniel

for 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) K080987

Device Name: **BridgePoint Medical Stingray™ Orienting Balloon Catheter**

Indications For Use:

The BridgePoint Medical Stingray™ Orienting Balloon Catheters are 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)

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Donna R. Vo Nguyen

(Division Sign-Off)
Division of Cardiovascular Devices

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