# 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:** K122795

NOV 8 2012

**Applicant Information:**

Date Prepared: September 11, 2012

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**Device Information:**

Classification: Class II Percutaneous Guidewire
Trade Name: Stingray™ Guidewire
Common Name: Percutaneous Guidewire
Classification Name: Percutaneous Guidewire

**Predicate Devices:**

The modified BridgePoint Medical Stingray™ Guidewires are substantially equivalent in intended use, method of operation and technical aspects to the following predicate device:

K081187 and K083727 – Stingray™ Guidewires
K102725 – BridgePoint Medical System consisting of the CrossBoss™ Catheter, Stingray™ Catheter and Stingray™ Guidewire

**Device Description**:
The modified Stingray™ Guidewires are conventionally constructed, single use, disposable guidewires that consist of a full-length stainless steel shaft with proximal PTFE coating where the distal portion of the stainless steel core 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 hydrophilic coated. The distal tip of the guidewire is supplied with an angled geometry which transitions to a conventional rounded tip. A short extension with an approximate diameter of 0.0035" (which is a monolithic extension of the core wire) extends approximately 0.007" distal of the rounded tip.

**Intended Use:**
The BridgePoint Medical Stingray™ Guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angiography (PTCA) and percutaneous transluminal angiography (PTA). The Stingray™ Guidewires are not to be used in cerebral blood vessels.

When used as part of the BridgePoint Medical System (consisting of the CrossBoss™ Catheter, Stingray™ Catheter, and Stingray™ Guidewire), the Stingray™ Guidewire is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

**Comparison to Predicate Device(s):**
The modified Stingray™ Guidewires are substantially equivalent to the previously cleared Stingray™ Guidewires, K081187 and K083727, in that they are all designed to facilitate placement of balloon dilatation catheters or other intravascular devices during PTCA and PTA procedures.

The Stingray™ Guidewires and previously cleared Stingray™ Guidewires are manufactured using the same processes and components and have similar physical attributes (flexibility, radiopacity, lubricity, tensile, torque, etc.). The distal tips of each device are radiopaque and can be seen with fluoroscopy for precise placement. All devices are highly lubricious for smooth delivery of multiple devices.

The modifications made to the originally cleared Stingray™ Guidewires include changes in the core wire material, colorant compound used in the proximal PTFE coating, and platinum tungsten coil diameter of the hydrophilic guidewires only (models M-3004 and M-3012). The core wire material is being modified from 304 stainless steel to 302 stainless steel. The PTFE colorant is being modified from chromium oxide green (CAS 1308-38-9) to cobalt titanate green (CAS 68186-85-6). Both of the new materials (core wire and proximal coating colorant) are currently used on other legally marketed devices within the same classification regulation for the same intended use. The distal platinum tungsten coil diameter is being modified from 0.0025" to 0.0020".

**Performance Data:**
The modified Stingray™ Guidewires have been evaluated using the following *in vitro* bench testing to confirm the performance characteristics as compared to the predicate device:

- Tensile
- Dimensional
- Guidewire Insert & Withdrawal
- Flexibility
- Fatigue
- Coating
- Torque
- Surface Defects
- Tip Memory, and
- Corrosion

*In vivo* testing was not deemed necessary based on the significance of the proposed modifications to the baseline device. The modified proximal coating formulation, core wire material, and distal coil dimensions result in a device that meets the original design requirements of the currently marketed Stingray™ Guidewires as demonstrated in the bench tests above. Animal studies were successfully completed with the currently marketed Stingray™ Guidewires.

Biocompatibility tests were completed to ensure all materials utilized to construct the modified Stingray™ Guidewires were biocompatible. Biocompatibility tests included:

- Cytotoxicity
- Kligman Sensitization
- Irritation
- Acute Systemic Cytotoxicity
- Pryogen
- Hemocompatibility
- *In Vitro* Hemocompatibility
- Complement Activation Assay (Direct)
- *In Vivo* Thrombogenicity, and
- Unactivated Partial Thromboplastin Time.

All results demonstrated the materials, manufacturing processes, and design of the modified Stingray™ Guidewires met the established performance criteria and will perform as intended.

**Summary:**

Based upon the intended use and descriptive information provided in this pre-market notification, the modifications to the BridgePoint Stingray™ Guidewires have 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 Center – WO66-G609
Silver Spring, MD 20993-002

BridgePoint Medical
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NOV 8 2012

Re: K122795
Trade/Device Name: Stingray Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Percutaneous Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: October 10, 2012
Received: October 11, 2012

Dear Jill 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

# 8. INDICATIONS FOR USE STATEMENT

**510(k) Number:** (TBA) K122795

**Device Name:** **BridgePoint Medical Stingray™ Guidewires**

**Indications For Use:**

The BridgePoint Medical Stingray™ Guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Stingray™ Guidewires are not to be used in the cerebral blood vessels.

When used as part of the BridgePoint Medical System (consisting of the CrossBoss™ Catheter, Stingray™ Catheter, and Stingray™ Guidewire), the Stingray™ Guidewire is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122795

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