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: K083727

FEB 20 2009

Applicant Information:

Date Prepared:	December 12, 2008
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 Guidewire
Trade Name:	Stingray™ Guidewire
Common Name:	Percutaneous Guidewire
Classification Name:	Percutaneous Guidewire

Predicate Devices:

The BridgePoint Medical stiff model Stingray™ Guidewire is substantially equivalent in intended use, method of operation and technical aspects to the following predicate devices:

K081187 – standard model Stingray™ Guidewire (f.k.a. Entera™ Percutaneous Coronary Guidewire)
K041531 – Confianza Pro Asahi PTCA Guidewire
K970396 – Triumph™ PTCA Guidewire

Device Description:

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. 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 angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Stingray™ Guidewires are not to be used in cerebral blood vessels.

Comparison to Predicate Devices:

The BridgePoint stiff model Stingray™ Guidewire is substantially equivalent to the standard model Stingray™ Guidewire, K081187, the Confianza Pro Asahi PTCA Guidewire, K041531, and the Triumph™ PTCA Guidewire, K970396 in that they are all designed to facilitate placement of balloon dilatation catheters or other intravascular devices during PTCA.

The BridgePoint Medical stiff model Stingray™ Guidewire is not just substantially equivalent, but is exactly the same as the K081187 – standard model Stingray™ Guidewire, with the only exceptions being the length of the grind/tapers required to produce the desired wire flexibility/support and the removal of the outer distal coil from the distal tip of the wire. The stiff and standard model Stingray™ Guidewires are manufactured using the same processes. The stiff and standard models are produced using the same component materials (core wire, coil, coatings, solder etc.) and have similar physical attributes (flexibility, radiopacity, lubricity, extension wire compatibility, etc).

The distal tips of each device are radiopaque and can be seen with fluoroscopy for precise placement. Both devices are highly lubricious for smooth delivery of multiple devices. They both have stainless steel core wires.

Summary:

Based upon the intended use, description information, and performance evaluation provided in this pre-market notification, the BridgePoint Medical stiff model Stingray™ Guidewires have 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

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

FEB 20 2009

Re: K083727
Trade/Device Name: Stingray™ Guidewire, Stiff
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Dated: January 16, 2009
Received: January 21, 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 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. Vachuy

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)~~ K083727

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

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 cerebral blood vessels.

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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Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

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