3. 510(k) SUMMARY

OCT 0 8 2008

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 K081187

Applicant Information:

Date Prepared: April 26, 2008

Name: BridgePoint Medical
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Contact Person: Michael A. Daniel
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Facsimile Number: (925) 254-5187

Device Information:

Classification: Class II Percutaneous Guidewire / DQX / 870.1330
Trade Name: BridgePoint Medical Entera™ Percutaneous Coronary and Peripheral Guidewire
Common Name: Percutaneous Guidewire
Classification Name: Percutaneous Guidewire

Predicate Devices:

The BridgePoint Medical Entera Guidewire is substantially equivalent in intended use, method of operation and technical aspects to a combination of the following predicate devices:

K970376 - Lake Region PTCA guidewire/Triumph
K073082 - Cordis/Brivant, Ltd. Regatta Steerable Guidewire
K041531 - Asahi PTCA Guidewire Confianza Pro

Device Description:

The Entera 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 coaxially positioned coils, constructed of stainless steel and Pt/W for visibly under fluoroscopy. The coils are fixed to the stainless core via silver alloy solder and are optionally coated with silicone (Lake Region Medical MDX). The distal tip of the guidewire is supplied in a straight or angled geometry which transitions to a conventional rounded tip. A short extension with an approximate diameter of 0.0032" (which is a monolithic extension of the core wire) extends approximately 0.007" distal of the Entera rounded tip.

Intended Use:

The BridgePoint Medical Entera 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 Entera guidewires are not to be used in cerebral blood vessels.

Comparison to Predicate Devices:

The BridgePoint Entera guidewire is substantially equivalent to the Lake Region PTCA guidewire/Triumph (K970376), the Cordis/Brivant, Ltd. Regatta Steerable Guidewire (K073082), and the Asahi PTCA Guidewire Confianza Pro (K041531). Each of these devices are designed to facilitate placement of balloon dilatation catheters or other intravascular devices during PTCA / PTA procedures.

The BridgePoint Medical Entera guidewire is not just substantially equivalent, but is exactly the same as the Lake Region Steerable Guidewire (K970376) currently marketed by Lake Region Medical under the trade name Triumph™, with two exceptions:

1) The Entera has a narrowed extension on its distal tip that is less than 0.014" in diameter while the Triumph™ has a standard 0.014" distal tip, and,

2) the distal most portion of the Entera core wire (the section that resides under the distal coil) has a round cross section while the Triumph has a flattened or ribbon cross section.

The Entera and Triumph are manufactured by Lake Region Medical. The Triumph and Entera are produced using the same component materials (core wire, coil, coatings, solder etc.) and have very similar physical attributes (flexibility, radiopacity, lubricity, etc). In terms of the distal tip geometries; the Lake Region Medical distal tip includes a conventional soldered and rounded .014" profile tip, while the Entera guidewire includes a very short portion of core wire that extends past the soldered and rounded distal tip. This extension is approximately 0.0032" in diameter and 0.007" in length.

The BridgePoint Entera guidewire has a distal tip geometry that is substantially equivalent to the narrowed distal tip geometries of the Cordis/Brivant, Ltd. Regatta Steerable Guidewire, and the Asahi PTCA Guidewire Confianza Pro. The Cordis Regatta has a non-conventional narrowed "wedge shaped" tip that tapers to a dimension that is substantially less than 0.014" (exact dimension unknown). The Confianza Pro has a distal tip that gradually tapers to a 0.009" diameter.

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

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the BridgePoint Entera device 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

OCT 0 8 2008

BridgePoint Medical
c/o Michael A. Daniel
Regulatory/Clinical Affairs Consultant
Daniel & Daniel Consulting
8 Snowberry Court
Orinda, CA 94563

Re: K081187
Trade/Device Name: Entera™ Percutaneous Coronary and Peripheral Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Dated: September 26, 2008
Received: September 29, 2008

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. Vachner

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

Enclosure

Indications for Use

510(k) Number: (TBA) K081187

Device Name: **BridgePoint Medical Entera Device**

Indications For Use:

The BridgePoint Medical Entera guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PCTA) and percutaneous transluminal angioplasty (PTA). The Entera 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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Donna R. Vorhees
(Division Sign-Off)
Division of Cardiovascular Devices

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