K083657

Conquest™ PTA Balloon Dilatation Catheter

510(k) Summary
21 CFR 807.92

DEC 24 2008

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski, Associate Project Manager, Regulatory Affairs

Date November 13, 2008

Subject Device Name:

Device Trade Name:	**Conquest™ PTA Balloon Dilatation Catheter**
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- Conquest™ PTA Balloon Dilatation Catheter (K014212; cleared January 17, 2002)
- Dorado™ PTA Balloon Dilatation Catheter (K072283; cleared September 19, 2007)
- Edwards Peripheral Dilatation Catheter (K052149; cleared September 2, 2005)

K083657

Device Description:

The Conquest™ PTA Balloon Dilatation Catheter is composed of a coaxial lumen catheter. One lumen accommodates a guidewire for catheter tracking and the second provides a channel for balloon inflation/deflation.

A composite balloon is mounted onto the distal tip of the catheter. During use, the balloon position in the vessel is identified by two radiopaque platinum iridium marker bands that indicate the working length of the balloon and aid in placement.

Indications for Use of Device:

The Conquest™ PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Comparison of Indications for Use to Predicate Devices:

The indication for use statement for the Conquest™ PTA Balloon Dilatation Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices, the Conquest™ PTA Balloon Dilatation Catheter, the Dorado™ PTA Balloon Dilatation Catheter and the Edwards Peripheral Dilatation Catheter. Therefore, the subject device, the Conquest™ PTA Balloon Dilatation Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The Conquest™ PTA Balloon Dilatation Catheter has the following similarities to the predicate devices:

- Similar intended use (all predicates)
- Similar indications for use (all predicates)
- Same target population (all predicates)
- Same fundamental scientific technology (all predicates)
- Same operating principle (all predicates)

- Same packaging materials and configuration (Conquest™ PTA Balloon Dilatation Catheter)
- Same sterility assurance level and method of sterilization (Conquest™ PTA Balloon Dilatation Catheter and Dorado™ PTA Balloon Dilatation Catheter)

Conclusions:
The subject device, the Conquest™ PTA Balloon Dilatation Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Conquest™ PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Conquest™ PTA Balloon Dilatation Catheter, the Dorado™ PTA Balloon Dilatation Catheter, and the Edwards Peripheral Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 2008

Bard Peripheral Vascular, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K083657
Conquest PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 9, 2008
Received: December 10, 2008

Dear Mr. Mosenkis:

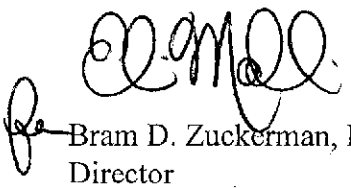
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

510(k) Number (if known):

Device Name: Conquest™ PTA Balloon Dilatation Catheter

Indications for Use: The Conquest™ PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 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 K083657