Dorado™ PTA Balloon Dilatation Catheter

510(k) Summary of Safety and Effectiveness
21 CFR 807.92

SEP 19 2007

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 summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street P.O. Box 1740 Tempe, Arizona 85280
Phone:	480-303-2524
Fax:	480-449-2546
Contact:	Genevieve Balutowski, Senior Regulatory Affairs Specialist
Date	July 18, 2007

Subject Device Name:

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

Predicate Devices:

- Conquest™ PTA Balloon Dilatation Catheter (K014212, cleared January 17, 2002), manufactured by Bard Peripheral Vascular, Inc.
- Ultraverse® Small Vessel PTA Balloon Dilatation Catheter (K012913, cleared September 28, 2001), manufactured by Bard Peripheral Vascular, Inc.

- Sterling™ Over-The-Wire PTA Balloon Dilatation Catheter (K053116, cleared December 16, 2005), manufactured by Boston Scientific Corporation.

- PolarCath™ Peripheral Dilatation System (K060572, cleared March 15, 2006), manufactured by Boston Scientific Corporation.

Device Description:

The subject device, the Dorado™ PTA Balloon Dilatation Catheter, is composed of a multi-lumen catheter with 5 or 5.8 French shaft outer diameter, depending on balloon size. 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 marker bands that indicate the working length of the balloon and aid in placement.

Intended Use of Device:

Dilatation of stenosis in the peripheral vascular, for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and post-deployed stent expansion of self-expanding and balloon expandable peripheral vascular stents.

Indications for Use of Device:

The Dorado™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. This catheter is not for use in the coronary arteries.

Comparison of Indications for Use to Predicate Devices:

The Indications for Use of the Dorado™ PTA Balloon Dilatation Catheter is a combination of the Indications for Use of the predicate devices. Therefore, while the indications statement of the subject and predicate devices are different, the differences do not affect the safety and effectiveness of the device when used as labeled as all the indications of the subject device are cleared for similar legally marketed devices.

Technological Comparison to Predicate Devices:

The Dorado™ 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)
- Similar fundamental scientific technology (all predicates)
- Similar operating principle (all predicates)
- Similar packaging materials (Conquest™ PTA Balloon Dilatation Catheter and Ultraverse® Small Vessel PTA Balloon Dilatation Catheter)
- Same sterility assurance level and method of sterilization (Conquest™ PTA Balloon Dilatation Catheter and Ultraverse® Small Vessel PTA Balloon Dilatation Catheter)

Conclusions:

The Dorado™ 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 Dorado™ PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Conquest™ PTA Balloon Dilatation Catheter, the Bard Ultraverse® Small Vessel Balloon Dilatation Catheter, the Sterling™ Over-The-Wire PTA Balloon Dilatation Catheter, and the PolarCath™ Peripheral Dilatation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

Bard Peripheral Vascular, Inc.
c/o Mr. Genevieve Balutowski
Senior Regulatory Affairs Specialist
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K072283
Dorado™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, LIT
Dated: September 5, 2007
Received: September 6, 2007

Dear Mr. Balutowski:

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 Biometric's (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. Zuckerman

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): K072283

Device Name: Dorado™ PTA Balloon Dilatation Catheter

Indications for Use: The Dorado™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. This catheter is not for use in the 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)

Donna R. Mahmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072283