Ultraverse® RX PTA Dilatation Catheter

510(k) Summary
21 CFR 807.92

MAY 3 0 2013

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: 480-350-6014

Fax: 480-449-2546

Contact: Mario Thomas, Regulatory Affairs

Date February 27, 2013

Subject Device Name:

Device Trade Name:	**Ultraverse® RX PTA Dilatation Catheter**
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code LIT)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Device:

- Ultraverse 014/018 PTA Balloon Dilatation Catheter (K121856, cleared July 11, 2012)
- Clearstream LitePAC RX PTA Catheter (K100490, cleared March 16, 2010)

Device Description:

The Ultraverse® RX PTA Dilatation Catheter is a small vessel balloon catheter consisting of a rapid exchange catheter and a balloon fixed at the distal tip. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The device will come in 80, 150, and 200 cm catheter shaft lengths. On the 150 and 200 cm catheter shaft lengths, two non-radiopaque markers are located 90 cm and 100 cm from the balloon catheter tip to help confirm when the balloon catheter tip exits the introducer sheaths or guide catheters. The catheter includes a radiopaque atraumatic tip and the Ultra-Cross™ Dual Layer Hydrophilic Coating (as used on Ultraverse 014/018) on the distal segment of the catheter shaft and balloon to facilitate advancement of the catheter to and through the stenosis. Ultraverse® RX Catheters are compatible with .014" guidewires. The proximal portion of the catheter includes a female luer lock hub connected to the catheter.

Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A stylet is placed into the tip of the catheter to aid in rewrap/refolding of the balloon. A flushing needle is provided for catheter prep. These products are not made with any natural rubber latex.

Indications for Use of Device:

The Ultraverse® RX PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries. This catheter is not for use in coronary arteries.

Comparison of Indications for Use to Predicate Devices:

The indication for use statement for the Ultraverse® RX PTA 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. Therefore, the subject device, the Ultraverse® RX PTA Dilatation Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The Ultraverse® RX PTA Dilatation Catheter has the following similarities to the predicate device:

- Same intended use (Same as Ultraverse 014/018 predicate device)
- Similar indications for use (combines LitePAC and Ultraverse 014/018 predicate devices)
- Same target population (Same as Ultraverse 014/018 predicate device)
- Same operating principle (Same as LitePAC predicate)
- Similar materials (Combination of LitePAC and Ultraverse 014/018 materials)
- Same fundamental scientific technology (Same as all predicates)
- Similar packaging materials and configurations (Similar to all predicates)
- Same sterility assurance level and method of sterilization (Same as all predicates)

Performance Data:

To demonstrate substantial equivalence of the subject device, the Ultraverse® RX PTA Dilatation Catheter to the predicate device, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Dimensional Verification
  - Balloon Outer Diameter
  - Balloon Working Length
  - Hypotube Outer Diameter
  - Catheter Shaft Length
  - RX Junction Length
- Flushability
- Tip Taper
- Hub Torque
- Hub Stress
- Sheath Compatibility
- Reinsertion/Stylet/Refold
- Rated Burst Pressure

- Balloon Burst Mode
- Catheter Shaft Leaks
- Fatigue
- Balloon Distensibility
- Inflation Time
- Deflation Time
- Balloon to Shaft Tensile
- RX Junction Tensile
- Hub to Hypotube Tensile
- Trackability (Flexibility and Kink)
- Tip Radiopacity
- Marker Band Alignment
- Flushing Needle Stress
- Flushing Needle Torque
- Packaging Visual Inspection
- Dye Penetration

The results from these tests demonstrate that the technological characteristics and performance criteria of the Ultraverse® RX PTA Dilatation Catheter is comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market with the same intended use.

Biocompatibility:

To demonstrate substantial equivalence of the subject device, the Ultraverse® RX PTA Dilatation Catheter to the predicate device, the following biocompatibility testing was performed in accordance ISO 10993-1:2010, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process," and "Blue Book Memorandum – G95-1 Use of International Standard ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

- Cytotoxicity
- Irritation/Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity

- Material Mediated Pyrogenicity
- Hemocompatibility (Hemolysis and Thrombogenicity)

The results from these tests demonstrate that the subject device, the Ultraverse® RX PTA Dilatation Catheter, is comparable to the predicate device and that it is considered biocompatible for its intended use.

Conclusions:

The subject device, the Ultraverse® RX PTA 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 Ultraverse® RX PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 30, 2013

Bard Peripheral Vascular, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131199
Trade/Device Name: Ultraverse® RX PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: LIT
Dated: April 25, 2013
Received: April 26, 2013

Dear Mr. Job:

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 contact 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. 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,

Bram D. Zuckerman -S

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

Indications for Use

510(k) Number (if known):

Device Name: Ultraverse® RX PTA Balloon Dilatation Catheter

Indications for Use: Ultraverse® RX PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries. 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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