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

September 24, 2014

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

Re: K142261
Trade/Device Name: Ultraverse 035 PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 13, 2014
Received: August 14, 2014

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142261

Device Name

Ultraverse® 035 PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The Ultraverse® 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native or synthetic AV fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. 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 coronary arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Ultraverse® 035 PTA Dilatation Catheter

510(k) Summary
21 CFR 807.92

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 July 23, 2014

Subject Device Name:

Device Trade Name:	**Ultraverse® 035 PTA Dilatation Catheter**
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code LIT)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Device:

- Rival PTA Balloon Dilatation Catheter (K120722, cleared April 19, 2012)

Device Description:

The Ultraverse® 035 PTA Dilatation Catheter is a semi-compliant balloon catheter consisting of an over the wire (OTW) catheter with an angioplasty balloon fixed at the distal tip. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The catheter also includes a radiopaque, atraumatic tip. GeoAlign™ Marker Bands are designated on the catheter shaft by 1cm increment bands. Each 10cm increment is labeled with the distance from the distal balloon tip. Thicker bands denote the midway point (5cm) between the labeled distances. GeoAlign™ Marker Bands are designed to be used as a location reference tool. GeoAlign™ Marker Bands are also designed to be used as a guide to assist with geographic alignment when used with an adjunctive therapy that utilizes the same GeoAlign™ Marker Bands. The aforementioned design elements of the GeoAlign™ Marker Bands facilitate increased procedure efficiency and minimize fluoroscopy exposure. The Ultraverse® 035 PTA Dilatation Catheter is compatible with .035" guidewires. The proximal portion of the catheter includes a female luer lock hub connected to the catheter with a guidewire lumen and an inflation lumen. Packaged with every product is a protective sheath that is positioned over the balloon and should be removed prior to use. A stylet is placed into the tip of the catheter to aid in rewrap/refolding of the balloon. A re-wrapping tool is also provided on the catheter shaft. These products are not made with natural rubber latex.

Attribute	**Ultraverse® 035 PTA Dilatation Catheter Product Offering**
Balloon Diameter (mm)	3, 4, 5, 6, 7, 8, 9, 10, 12
Balloon Length (mm)	10, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300
Catheter Shaft Lengths (cm)	40, 75, 100, 130, 150
Introducer Sheath Compatibility Compatible Balloon Diameters and Lengths (mm x mm)	**5F**: 3.0 — 10, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300 4.0 — 10, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300

Attribute	Ultraverse® 035 PTA Dilatation Catheter Product Offering	
	5.0	10, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300
	6.0	10, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300
	7.0	10, 20, 40, 60, 80, 100, 120, 150, 200
	8.0	10, 20, 40, 60, 80
	6F: 7.0	250, 300
	8.0	100, 120, 150, 200
	9.0	10, 20, 40, 60, 80, 100
	10.0	10, 20, 40, 60, 80, 100
	7F: 8.0	250, 300
	12.0	10, 20, 40, 60, 80, 100

Indications for Use of Device:

The Ultraverse® 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native or synthetic AV fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. 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 coronary arteries.

Comparison of Indications for Use to Predicate Devices:

The indication for use statement for the Ultraverse® 035 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® 035 PTA Dilatation Catheter, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The Ultraverse® 035 PTA Dilatation Catheter has the following similarities to the predicate device:

- Similar intended use
- Similar indications for use
- Same target population
- Same operating principle
- Similar materials
- Same fundamental scientific technology
- Similar packaging materials and configurations
- Same sterility assurance level and method of sterilization

Performance Data:

To demonstrate substantial equivalence of the subject device, the Ultraverse® 035 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
    - Tip Length
    - Balloon Outer Diameter
    - Balloon Length
    - Shaft Outer Diameter
    - Catheter Shaft Length
- Gradient Marking Position
- Gradient Marking Legibility
- Gradient Marking Durability
- Trackability
- Sheath Compatibility
- Flushability

- Reinsertion
- Stylet/Refold
- Device Compatibility
- Guidewire Compatibility
- Balloon Distensibility
- Inflation
- Deflation
- Balloon Rated Burst Pressure
- Leak
- Burst Mode
- Fatigue
- Balloon Fatigue in a Stent/Stent Graft
- Balloon Burst in a Stent/Stent Graft
- Balloon Removal from a Stent/Stent Graft
- Balloon to Shaft Tensile
- Catheter Elongation
- Hub to Shaft Tensile
- Tip Taper
- Tip Radiopacity
- Marker Band Radiopacity
- Marker Band Alignment
- Hub Torque/Hub Stress
- Packaging
    - Visual Inspection
    - Dye Penetration
    - Pouch Tensile

The results from these tests demonstrate that the technological characteristics and performance criteria of the Ultraverse® 035 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® 035 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."

Biocompatibility Test	Test Method	Results
Cytotoxicity	MEM Elution Test	PASS
Sensitization	Murine Local Lymph Node Assay	PASS
	Guinea Pig Maximization Test	PASS
Intracutaneous	Intracutaneous Injection Test	PASS
Acute Systemic Toxicity	Systemic Injection Test	PASS
Hemocompatibility	In Vivo Hemolysis	PASS
	Thrombogenicity	PASS
	Complement Activation	
USP Pyrogen Study	Material Mediated Pyrogenicity	PASS

The results from these tests demonstrate that the subject device, the Ultraverse® 035 PTA Dilatation Catheter, is comparable to the predicate device and that it is considered safe and biocompatible for its intended use.

Conclusions:

The subject device, the Ultraverse® 035 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® 035 PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate devices.