October 3, 2019

Bard Peripheral Vascular, Inc.
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K192318
Trade/Device Name: Ultraverse 014 and 018 PTA Balloon Dilatation Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 23, 2019
Received: August 26, 2019

Dear Mr. Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters

Indications for Use *(Describe)*
Ultraverse® 014 and Ultraverse® 018 PTA Balloon Dilatation Catheters are recommended for use in percutaneous trasluminal angioplasty (PTA) of the renal, popliteal, tibial, femoral, and peroneal arteries. These catheters are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ultraverse® 014 and 018 PTA Balloon 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:	480-449-2587
Fax:	480-449-2546
Contact:	Andrew Quach, Regulatory Affairs Associate
Date	September 20, 2019

Subject Device Name:

Device Trade Name:	**Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters**
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal
Product Code:	LIT
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device:

- Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters (K121856; cleared July 11, 2012)

Reference Device:

- Ultraverse® 035 PTA Balloon Dilatation Catheters (K142261; cleared September 24, 2014)

Device Description:

The Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter is a small vessel balloon catheter consisting of an over the wire catheter with a balloon fixed at the distal tip. For all balloon lengths, radiopaque markers delineate the working length of the balloon and aid in balloon placement. For balloon lengths of 100 mm and greater, two radiopaque markers are positioned on the distal portion of the balloon and one radiopaque marker is positioned on the proximal portion of the balloon to differentiate between the distal and proximal ends of the balloon. The catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the stenosis as well as a hydrophilic coating. The coaxial lumen, over the wire catheter is compatible with an 0.014" guidewire for the 014 platform, and compatible with an 0.014" or 0.018" guidewire on the 018 platform, and is available in 75, 90, 100, 130, 150 and 200 cm working lengths. The proximal portion of the catheter includes a female luer lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen. 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. This product is not manufactured with any latex.

The GeoAlign® Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The GeoAlign® markings are designated on the catheter shaft by 1cm increment bands with an accuracy within ±1mm. The distance from the distal catheter tip is labeled in 10cm increments. Thicker bands denote the midway point (5cm) between the labeled distances. The GeoAlign® Marking System is designed to be used as a tool to externally measure the intravascular advancement and/or retraction of the catheter. This can provide an intravascular reference regarding the location of the distal tip of the catheter or an approximate intravascular length measurement between two points. The GeoAlign® Marking System may also facilitate geographic alignment of an adjunctive therapy that includes the same GeoAlign® Marking System.

Attribute	Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter
Balloon Diameter (mm)	1.5, 2 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9
Balloon Length (mm)	20, 40, 60, 80, 100, 120, 150, 200, 220, 250, 300
Catheter Shaft Length (cm)	75, 90, 100, 130, 150, 200
.014" Platform Introducer Sheath Compatibility	4F, 5F
.018" Platform Introducer Sheath Compatibility	4F, 5F, 6F

Indications for Use of Device:

The Ultraverse® 014 and Ultraverse ® 018 PTA Balloon Dilatation Catheters are recommended for use in percutaneous transluminal angioplasty (PTA) of the renal, popliteal, tibial, femoral and peroneal arteries. These catheters are not for use in coronary arteries.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter, are the same as compared to the predicate device. Therefore, the subject device, the Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The subject Ultraverse® 014 and 018 PTA Dilatation Balloon Catheters have the following similarities to the Ultraverse® 014 and 018 PTA Balloon Catheters predicate device (K121856 - cleared on July 11, 2012):

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

The subject device, Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters has the following differences when compared to the predicate device:

- Increased radiopaque marker bands lengths and additional marker band added to the distal end of the balloon for balloon lengths 100mm or longer
- GeoAlign® Marking System added along the shaft of the catheter
- Opaque colorant used instead of clear shaft color

- Strain relief on Ultraverse® 014 platform changed to blue color to differentiate product
- 0.014” guidewire compatibility for Ultraverse® 018 platform
- Extension of product size offering
- Extended 4Fr compatibility range

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, its technological characteristics and performance criteria 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:

- Catheter Shaft Length
- Balloon Working Length
- Marker Band Alignment
- Balloon OD at OP
- Balloon Rated Burst Pressure, Leak, & Burst Mode
- Crossing Profile
- Sheath Compatibility
- Shaft Outer Diameter
- Balloon Compliance / Distensibility
- Fatigue
- Hub to Shaft Tensile
- Guidewire Compatibility
- Inflation
- Deflation
- Balloon to Shaft Tensile
- Catheter Elongation
- Flushability
- GeoAlign® Marking Positions
- GeoAlign® Marking Durability
- GeoAlign® Marking Legibility
- Trackability
- Reinsertion
- Kink

The results from these tests demonstrate that the technological characteristics and performance criteria of the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

The following tests performed for the predicate device are leveraged as applicable tests for the subject device for components which remained unchanged from the predicate device:

- Radiopacity
- Tip Taper / Tip Length
- Stylet / Refold
- Hub Torsion / Hub Stress
- Device Compatibility
- Packaging Integrity
  - Packaging Visual Inspection
  - Dye Penetration
  - Pouch Seal Strength

Biocompatibility:

To demonstrate substantial equivalence of the subject device, the Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter to the predicate device, the following biocompatibility testing was performed in accordance ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Complement Activation, Thrombogenicity)
- Chemical Characterization

The results from these tests demonstrate that the subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, is comparable to the predicate device and that it is considered safe and biocompatible for its intended use.

Conclusions:

The subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters is substantially equivalent to the legally marketed predicate device.