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

June 14, 2017

Bard Peripheral Vascular, Inc.
Mr. Timothy Wade
Regulatory Affairs Project Manager
1625 West 3rd St
Tempe, AZ 85281

Re: K163420
Trade/Device Name: UltraScore Focused Force PTA Balloon
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PNO
Dated: May 4, 2017
Received: May 5, 2017

Dear Mr. Wade:

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" (21 CFR 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,

Fernando Aguel -S

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)*
K163420

Device Name
UltraScore Focused Force PTA Balloon

Indications for Use *(Describe)*
The UltraScore Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal 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 balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

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.

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ULTRASCORE™ Focused Force PTA Balloon 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:	480 638 2939
Fax:	480 449 2546
Contact:	Timothy Wade

Date	05 Dec 2016

Subject Device Name:

Device Trade Name:	**ULTRASCORE™ Focused Force PTA Balloon**
Regulation Number:	21 CFR 870.1250
Product Code:	PNO
Classification:	Class II
Classification Name:	Catheter, Percutaneous, Cutting/Scoring
Classification Panel:	Cardiovascular

Predicate Device:

- VASCUTRAK® PTA Dilatation Catheter (K103459; cleared December 13, 2010)

Reference Device:

- ULTRAVERSE® 035 PTA Dilatation Catheter (K142261; cleared September 24, 2014)

Device Description:

The ULTRASCORE™ Focused Force PTA Balloon consists of a flexible, over-the-wire (OTW) catheter shaft with a semi-compliant balloon fixed at the distal end. 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. Two scoring wires, oriented 180° apart, provide focused force upon dilatation. The ULTRASCORE™ Focused Force PTA Balloon is compatible with .014" or .035" guidewires, as denoted by the product labeling. The distal portion of the .014" guidewire compatible catheters is hydrophilically coated. 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 must be removed prior to use. A stylet is placed into the tip of the catheter. These products are not made with natural rubber latex.

Attribute	ULTRASCORE™ Focused Force PTA Balloon
Balloon Diameter (mm)	2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0. 8.0
Balloon Length (mm)	20, 40, 60, 80, 100, 120, 150, 200, 250, 300
Catheter Shaft Length (cm)	40, 75, 100, 130, 150
.014” Platform Introducer Sheath Compatibility	5F
.035” Platform Introducer Sheath Compatibility	6F

Indications for Use of Device:

The ULTRASCORE™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal 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 balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the ULTRASCORE™ Focused Force PTA Balloon does not raise any new issues of safety and effectiveness based on the proposed indications for use statement as compared to the predicate device. Therefore, the subject device, the ULTRASCORE™ Focused Force PTA Balloon, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The ULTRASCORE™ Focused Force PTA Balloon has the following similarities to the predicate device, the VASCUTRAK® PTA Dilatation Catheter (clearance to market via K103459 on December 13, 2010):

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

The ULTRASCORE™ Focused Force PTA Balloon has the following differences when compared to the VASCUTRAK® PTA Dilatation Catheter predicate device:

- Over-the-wire platform
- Additional 8.0mm balloon diameter offered
- New 0.035” guidewire compatibility offered
- Modifications to marker bands
- Material differences
- Addition of packaging stylet

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:

- Dimensional
  - Balloon Outer Diameter
  - Balloon Working Length
  - Catheter Shaft Length
- Balloon Compliance
- GEOALIGN® Gradient Marking Position
- GEOALIGN® Gradient Marking Legibility
- GEOALIGN® Gradient Marking Durability
- Trackability
- Sheath Compatibility
- Guidewire Compatibility
- Flushability
- Reinsertion
- Inflation Time
- Deflation Time
- Rated Burst Pressure
- Balloon Burst Mode
- Balloon Burst in Stent/Stent Graft
- Balloon Fatigue
- Balloon Fatigue in Stent/Stent Graft
- Balloon Removal from Stent/Stent Graft
- Tip Taper
- Device Compatibility
- Hub Stress
- Hub Torque
- Balloon to Shaft Tensile
- Tip to Wire Tensile
- Catheter Elongation
- Marker Band Radiopacity
- Marker Band Alignment
- Proximal Assembly Tensile
- Packaging Pouch Tensile
- Packaging Visual Inspection
- Packaging Bubble Emission

The following *in vitro* biocompatibility testing was conducted in accordance with ISO 10993-1: 2009

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility

- Material Mediated Pyrogenicity

The results from these tests demonstrate that the technological characteristics and performance criteria of the ULTRASCORE™ Focused Force PTA Balloon 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.

Conclusions:

The subject device, the ULTRASCORE™ Focused Force PTA Balloon, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The ULTRASCORE™ Focused Force PTA Balloon is substantially equivalent to the legally marketed predicate device, VASCUTRAK® PTA Dilatation Catheter.