January 20, 2023

C.R. Bard, Inc.
Andrew Quach
Senior Regulatory Affairs Specialist
1625 West 3rd St
Tempe, Arizona 85281

Re: K223177
Trade/Device Name: Highlander™ 014 PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: December 21, 2022
Received: December 22, 2022

Dear Andrew Quach:

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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.01.20 16:16:10 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223177

Device Name
Highlander™ 014 PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Highlander™ 014 PTA Balloon Dilatation Catheter is indicated for use in percutaneous transluminal angioplasty (PTA) of the peripheral vasculature, including femoral, popliteal, infra-popliteal and renal arteries. This device is also indicated 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Highlander™ 014 PTA Balloon Dilatation Catheter

510(k) Summary - K223177
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:	602-830-5680
Fax:	480-449-2546
Contact:	Andrew Quach, Senior Regulatory Affairs Specialist
Date	January 20, 2023

Subject Device Name:

Name of Device : Highlander™ 014 PTA Balloon Dilatation Catheter
Common or Usual Name: Catheter, Angioplasty, Peripheral, Transluminal
Classification Pro Code : LIT
Regulatory Class : Class II
Regulation Number : 21 CFR 870.1250

Predicate Device:

510(k) Number : K192318
Name of Device : Ultraverse™ 014 and 018 PTA Balloon Dilatation Catheters
Common or Usual Name: Catheter, Angioplasty, Peripheral, Transluminal
Classification Pro Code : LIT
Regulatory Class : Class II
Regulation Number : 21 CFR 870.1250

Reference Device:

510(k) Number : K072283
Name of Device : Dorado™ PTA Balloon Dilatation Catheter
Common or Usual Name: Catheter, percutaneous
Classification Pro Code : DQY, LIT
Regulatory Class : Class II
Regulation Number : 21 CFR 870.1250

Device Description:

The Highlander™ 014 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. The proprietary non-compliant, low-profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. For all balloon lengths, radiopaque markers delineate the working length of the balloon and aid in balloon placement. For balloon lengths of 100mm 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 catheters include an atraumatic tip to facilitate advancement of the catheter to and through the stenosis. A silicone-based, hydrophobic coating is present on the distal segment of the shaft and balloon. Highlander™ 014 is compatible with 0.014" guidewires. The proximal portion of the catheters include 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. These products are not made with natural rubber 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.

Indications for Use:

The Highlander™ 014 Balloon Dilatation Catheter is indicated for use in percutaneous transluminal angioplasty (PTA) of the peripheral vasculature, including femoral, popliteal, infra-popliteal and renal arteries. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. This catheter is not for use in coronary arteries.

Technological Comparison to Predicate Devices:

The subject Highlander™ 014 PTA Balloon Dilatation Catheter has the following similarities to the Ultraverse™ 014 and 018 PTA Balloon Dilatation Catheters predicate device (K192318 - cleared on October 3, 2019):

- Same intended use
- Similar indications for use
- Same target population

- Same operating principle
- Same fundamental scientific technology
- Same sterility assurance level
- Same method of sterilization

The subject device, Highlander™ 014 PTA Balloon Dilatation Catheter has the following differences when compared to the predicate device:

- Incorporation of non-compliant fiber balloon
- Change from hydrophilic coating to hydrophobic/silicone coating
- Change in colorant used on outer tubing
- Alternative hub & strain relief designs

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:

- Visual Inspection
- Catheter Length
- Tip Length
- Balloon Working Length
- Marker Band Alignment
- Balloon OD at OP
- Balloon Rated Burst Pressure, Leak, & Burst Mode
- Burst in Stent
- Crossing Profile
- Sheath Compatibility
- Shaft Outer Diameter
- Distensibility
- Luer Lock Compatibility
- Fatigue
- Fatigue in Stent
- Hub to Shaft Tensile
- Shaft Inner Diameter/ Guidewire Compatibility
- Inflation
- Deflation
- Particulate
- Coating Integrity
- Coating Length
- Balloon to Shaft Tensile
- Tip Tensile
- Catheter Elongation
- Flushability
- GeoAlign™ Marking Position
- GeoAlign™ Marking Durability
- GeoAlign™ Marking Legibility
- Trackability
- Reinsertion
- Kink Resistance
- Torque Response
- Packaging Integrity Visual Inspection
- Bubble Emission Leak
- Pouch Seal Strength
- Heat Seal Visual Inspection
- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility

The results from these tests demonstrate that the technological characteristics and performance criteria of the Highlander™ 014 PTA Balloon Dilatation Catheter 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 Highlander™ 014 PTA Balloon Dilatation Catheter, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Highlander™ 014 PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device, Ultraverse™ 014 and 018 PTA Balloon Dilatation Catheters.