June 17, 2025

Bard Peripheral Vascular, Inc.
Joan Bergstrom
Associate Regulatory Affairs Strategist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K250219
Trade/Device Name: Dorado™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, LIT
Dated: January 24, 2025
Received: January 24, 2025

Dear Joan Bergstrom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by
ARIEL G. ASH-SHAKOOR
-S
Date: 2025.06.17
10:59:08 -04'00'

For

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250219

Device Name
Dorado™ PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
Dorado™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian 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 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.

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.

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510(k) Summary

Dorado™ 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:	602-830-5357
Fax:	312-949-0436
Contact:	Joan Bergstrom, Regulatory Affairs Strategist
Date	January 24, 2025

Subject Device Name:

Device Trade Name:	**Dorado™ PTA Balloon Dilatation Catheter**
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal/ Catheter, Percutaneous
Product Code:	DQY, LIT
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device:

- Dorado™ PTA Balloon Dilatation Catheter (K072283 cleared September 19, 2007)

Reference Devices:

- Conquest™ 40 PTA Dilatation Catheter, Atlas™ Gold PTA Dilatation Catheter, Vida™ PTV Dilatation Catheter, Vida™ BAV Balloon Valvuloplasty Catheter (K212588 cleared May 4, 2022)

Device Description: The Dorado™ PTA Balloon Dilatation Catheter is a high-performance 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. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the stenosis. The novel catheter consists of a distal triple lumen and a proximal coaxial lumen and is designed to optimize the balance between pushabilty and trackability. The over the wire catheter is compatible with 0.035" guidewire and is available in 40, 80, 120, and 135 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 re-wrapping tool is also provided on the catheter shaft. 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.

List of Various Configurations: Dorado™ PTA Balloon Dilatation Catheter is available in a variety of introducer sheath size, balloon diameter, balloon length, and catheter shaft length combinations.

<table>
<tr><th>Attribute</th><th colspan="3">Dorado™ PTA Balloon Dilatation Catheter Product Offerings</th></tr>
<tr><td>Balloon Diameter (mm)</td><td colspan="3">3, 4, 5, 6, 7, 8, 9, 10</td></tr>
<tr><td>Balloon Length (cm)</td><td colspan="3">1.5, 2, 3, 4, 6, 8, 10, 12, 15, 17, 20</td></tr>
<tr><td>Catheter Shaft Lengths (cm)</td><td colspan="3">40, 80, 120, 135</td></tr>
<tr><td rowspan="6">Introducer Sheath Compatibility</td><td>Recommended Introducer (Fr)</td><td>Balloon Diameter (mm)</td><td>Balloon Length (cm)</td></tr>
<tr><td rowspan="3">5</td><td>3</td><td>2, 4, 10</td></tr>
<tr><td>4</td><td>2, 4, 10</td></tr>
<tr><td>5</td><td>1.5, 2, 3, 4, 6, 8, 10</td></tr>
<tr><td rowspan="2">6</td><td>4</td><td>12, 15, 17, 20</td></tr>
<tr><td>5</td><td>12, 15, 17, 20</td></tr>
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Attribute	Dorado™ PTA Balloon Dilatation Catheter Product Offerings		
		6	1.5, 2, 3, 4, 6, 8, 10, 12, 15, 17, 20
		7	1.5, 2, 3, 4, 6, 8, 10, 12, 15, 17, 20
		8	1.5, 2, 3, 4, 6, 8, 10
		9	2, 3, 4, 8
		10	2, 3, 4
	7	10	8

Indications for Use:

Dorado™ Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian 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 and self-expanding stents in the peripheral vasculature. This catheter is not for use in coronary arteries.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Dorado™ Balloon Dilatation Catheter, is the same as compared to the predicate device.

Technological Comparison to Predicate Device:

The subject device, Dorado™ Balloon Dilatation Catheter, is the same as the predicate, the previously cleared Dorado™ Balloon Dilatation Catheter (K072283) in the following aspects:

- Same indications for use
- Same target patient population
- Same principle of operation
- Same fundamental scientific technology
- Same packaging materials and configurations

- Same sterility assurance level and method of sterilization
- Similar materials
- Same design specifications (with the exception of Balloon Lengths and Tip Length, explained herein)

The subject device has the following difference as compared to predicate device:

- A Pebax Grade Material change

The subject device was also modified with the following minor changes that did not warrant a 510(k) submission:

- A Line Extension Change which included dimensional, material and packaging changes
- A Tip Configuration change

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, 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:

- Trackability
- Minimum Balloon Burst Strength and Balloon Failure Mode
- Balloon Fatigue
- Fatigue in Stent (Puncture Resistance)
- Sheath Compatibility
- Dimensional Verification
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Compliance (Diameter vs Pressure)
- Balloon Inflation and Deflation time
- Catheter Bond Strength
- Tip Pull Test
- Torque Strength
- Radiopacity

The following in vitro biocompatibility testing was conducted in accordance with ISO 10993-1:2018:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Toxicity
- Systemic Toxicity
- Hemocompatibility
    - Hemolysis
    - Thrombogenicity
    - Complement Activation

Conclusion:

The subject device, Dorado™ 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 conclusions drawn from the nonclinical tests demonstrate that the Dorado™ PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device.