February 4, 2026

Bard Peripheral Vascular, Inc.
Laurissa Brantley
Regulatory Affairs Specialist
1625 W. 3rd St.
Tempe, Arizona 85281

Re: K260012
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: January 2, 2026
Received: January 5, 2026

Dear Laurissa Brantley:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.02.04 15:23:36 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260012

Device Name
The 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.

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:

Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 602-830-5578

Contact Person: Laurissa Brantley, Regulatory Affairs Specialist
Date of Submission: January 2, 2026

Subject Device Name:

Name of Device:	**UltraScore™ Focused Force PTA Balloon**
Product Code:	PNO
Classification Name:	Catheter, Percutaneous, Cutting/Scoring
Regulatory Class:	Class II
Regulation Number:	21 CFR 870.1250

Predicate Device:

Name of Device:	**UltraScore™ Focused Force PTA Balloon (K172571, Cleared September 22, 2017)**
Product Code:	PNO
Classification Name:	Catheter, Percutaneous, Cutting/Scoring
Regulatory Class:	Class II
Regulation Number:	21 CFR 870.1250

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 0.014" or 0.035" guidewires, as denoted by the product labeling. The distal portion of the 0.014" 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 (cm)	20, 40, 60, 80, 100, 120, 150, 200, 250, 300
Catheter Shaft Length (cm)	40, 75, 100, 130, 150
.014” Platform Introducer Sheath Compatibility	4F, 5F
.035” Platform Introducer Sheath Compatibility	5F, 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 is identical to that of 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 is identical to the predicate device, the UltraScore™ Focused Force PTA Balloon (clearance to market via K172571 on September 22, 2017) in the following ways:

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

The following change has been made been made between the subject device and the predicate device:

- A new formulation of PTFE on the scoring wires has been qualified due to supplier discontinuance of existing PTFE.

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:

- Sheath Compatibility
- Inflation Time
- Deflation Time

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
- Thrombogenicity
- Chemical Characterization

The remaining performance data has been leveraged from the 510(k) submission, K163420 (cleared June 14, 2017).

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, UltraScore™ Focused Force PTA Balloon.