March 1, 2021

C.R. Bard, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K203275
Trade/Device Name: Recon Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 24, 2021
Received: February 25, 2021

Dear 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,

Lydia Glaw
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)*
K203275

Device Name
Recon™ Support Catheter

Indications for Use *(Describe)*
The Recon™ Support Catheters are single lumen catheters intended to create a pathway for other devices 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.

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

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K203275

Recon™ Support 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 1625 West 3rd Street Tempe, Arizona 85281
Phone:	(480) 597-8252
Fax:	(480) 449-2546
Contact Person:	Andrew Quach, Regulatory Affairs Specialist
Date of Submission:	October 7, 2020

Subject Device Name:

Name of Device:	Recon™ Support Catheter
Common or Usual Name:	Support Catheter
Classification Name:	Percutaneous catheter
Classification Panel:	Cardiovascular
Regulatory Class:	II
Regulation Number:	870.1250
Product Code:	DQY

Predicate Device:

510(k) Number:	K161986 & K131493
Name of Device:	Sidekick™ & Usher™ Support Catheters
Common or Usual Name:	Percutaneous catheter
Classification Name:	Catheter, Percutaneous
Regulatory Class:	II
Regulation Number:	870.1250

Device Description:

The Recon™ Support Catheters are single lumen catheters with a standard luer fitting hub and separate detachable hemostatic valve to guide and provide support for the Crosser™ Ultrasonic CTO Device. The product hub identifies the BD logo and sheath profile (6F) on one side and on the opposite side, the product hub identifies the working length of catheter in centimeters (110 cm) and S for Straight and A for Angled, and T for Tapered.

The Recon™ Support Catheters are available in angled and straight, tapered and non-tapered configurations in 110 cm working lengths. The Recon™ Support Catheter has a single radiopaque marker 1mm from the distal tip.

The GeoAlign™ Marking System is a non-radiopaque ruler on the catheter shaft referenced from the distal tip. The GeoAlign™ markings are designated on the catheter shaft by 1 cm increment bands with an accuracy within ±1 mm. The distance from the distal catheter tip is labeled in 10 cm increments. Thicker bands denote the midway point (5 cm) 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. The GeoAlign™ Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy. The GeoAlign™ Marking System includes non-radiopaque white markings and is designed to be utilized outside the sheath.

Intended Use/Indications for Use:

The Recon™ Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

Contraindications:

The Recon™ Support Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

Technological Comparison to Predicate Devices:

The Recon™ Support Catheter has the following similarities to the predicate devices:

- Same intended use
- Same indications for use
- Same target population
- Same fundamental scientific technology
- Same operating principle
- Same sterility assurance level and method of sterilization
- Same colorant/materials for shaft as Usher™ Support Catheter
- Same product configurations

The subject device, Recon™ Support Catheter, incorporates the following changes:

- Hub design and materials
- Tip to use the same material/colorant as the shaft as a single extrusion
- Updated taper design
- Changed hemostasis valve
- Guidewire introducer not included with product
- Minor updates to packaging design and materials to accommodate product changes

Performance Data:

To demonstrate substantial equivalence of the subject device, the Recon™ Support Catheter, to the predicate devices, the technological characteristics and performance criterion 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:

- Interventional Device Testing Equipment (IDTE) Track
- Manual Track
- Kink Diameter
- Torsional Stiffness
- Hemostasis Valve Leakage
- Radiopacity
- Hub to Shaft Tensile
- Shaft Tensile
- Leakage
- Hub Positive Pressure Leak
- Hub Stress Cracking
- Hub Sub-Atmospheric Pressure Leak
- Luer Resistance to Axial Separation
- Luer Resistance to Unscrewing Torque
- Luer Resistance to Thread Override
- Particulate
- Guidewire Compatibility
- Sheath Compatibility
- Crossing Device Trackability through Recon™ Catheter
- Crossing Device Crossing Efficiency through Recon™ Catheter
- Burst Strength
- High Pressure Leak
- Packaging Tests (pouch visual, bubble emission leak, pouch tensile)

The following test performed for the predicate device was leveraged as an applicable test for the subject device for components which remained unchanged from the predicate device (performed as part of K161986):

- GeoAlign™ Testing (Legibility, Durability, Compatibility, Dimensional Analysis)

Biocompatibility:

To demonstrate substantial equivalence of the subject device, the Recon™ Support Catheter, to the predicate device, biocompatibility tests were performed in accordance with ISO 10993-1:2018, “Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process.”

- Cytotoxicity
- Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis (Hemocompatibility)
- Complement Activation
- Partial Thromboplastin Time (PTT)
- In Vivo Thromboresistance
- Chemical Characterization (GC/LS/ICP)

The results from these tests demonstrate that the technological characteristics and performance criteria of the Recon™ Support Catheter is comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the similar intended use.

Conclusions:

The Recon™ Support Catheter met all the 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 and clinical tests that demonstrate that the Recon™ Support Catheter is as safe, as effective, and performs as well as or better than the Sidekick™ and Usher™ Support Catheters.