April 2, 2021

C. R. Bard, Inc.
Arieona Boyle
Regulatory Affairs Specialist
1625 West Third Street
Tempe, AZ 85281

Re: K203767
Trade/Device Name: Pristine™ Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: February 26, 2021
Received: March 1, 2021

Dear Arieona Boyle:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Carolyn Y. Neuland -S

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203767

Device Name
Pristine™ Long-Term Hemodialysis Catheter

Indications for Use *(Describe)*
The Pristine™ Long-Term Hemodialysis Catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, apheresis and infusion. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 40 cm implant length are indicated for femoral vein insertion. Catheters may be inserted percutaneously.

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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Pristine™ Long-Term Hemodialysis 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: 480-597-8260

Fax: 312-949-0436

Contact: Arieona Boyle, Regulatory Affairs Specialist

Date December 22, 2020

Subject Device Name:

Device Trade Name:	Pristine™ Long-Term Hemodialysis Catheter
Common or Usual Name:	Catheter, Hemodialysis, Implanted
Device Classification:	Class II
Classification Name:	Blood Access Device and Accessories
Product Code:	MSD
Regulation Number:	21 CFR 876.5540
Classification Panel:	Gastroenterology/Urology

Predicate Device:

Pristine™ Hemodialysis Catheter (K182443, cleared May 31, 2019)

Reference Device:

GlidePath™ Long-Term Hemodialysis Catheter (K190527, cleared March 05, 2020)

Device Description:

The Pristine™ Long-Term Hemodialysis Catheter is a chronic hemodialysis catheter consisting of a dual lumen radiopaque shaft with a pre-formed split tip, which enables long-term vascular access for hemodialysis, apheresis, and infusion. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the catheter bifurcation and suture wings (hub). The distal end of the catheter hub is connected to the dual lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical split tip. The design of the catheter's distal tip includes a split, symmetric Y-Tip™ with notches and without side-holes or slots. The symmetric Y-Tip™ design allows a spatial separation between the distal ends of the two lumens. The Pristine™ Long-Term Hemodialysis Catheter is provided as a sterile, single use device, and is sterilized using a validated ethylene oxide process. The dialysis catheters are offered in various implant lengths, varying from 19 cm to 55 cm as depicted below.

Attribute	Pristine™ Hemodialysis Catheter Product Offerings
Catheter Outer Diameter (F)	15.5
Catheter Shaft Length, Tip to Cuff (cm)	19, 23, 28, 33, 55
Catheter Shaft Length, Tip to Hub (cm)	24, 28, 33, 38, 60
Overall Catheter Length (cm)	35, 39, 44, 49, 71

Indications for Use of Device:

The Pristine™ Long-Term Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, apheresis and infusion. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 40 cm implant length are indicated for femoral vein insertion. Catheters may be inserted percutaneously.

Comparison to Predicate Device and Reference Device:

The subject Pristine™ Long-Term Hemodialysis Catheter has the following similarities to the predicate Pristine™ Hemodialysis Catheter (K182443, cleared May 31, 2019):

- 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 subject Pristine™ Long-Term Hemodialysis Catheter has the following similarities to the reference GlidePath™ 14.5F Long-Term Hemodialysis Catheter (K190527, cleared March 05, 2020):

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

The subject Pristine™ Long-Term Hemodialysis Catheter has the following differences to the Predicate, Pristine™ Hemodialysis Catheter (K182443, cleared May 31, 2019):

- Modified Luer geometry - removal of excessive material (wings) from the external surface of the Luer
- Removal/elimination of the quantity of two process aid materials used in the extension legs extrusion process
- Reducing the external thickness on the center of the bifurcation by 0.2 mm
- Modified packaging configuration with addition of catheter tip holder for packaging purposes
- Different sterilization facilities and manufacturing plant as a result of acquisition by Bard
- Expanded standard components
- Modified tunneler design
- Addition of ID tags to device clamps, removal of printing on the device luers, and modified printing on the bifurcation

The subject device incorporates the same intended use, indications for use, target population, operating principle, fundamental scientific technology and a similar design and materials as the predicate Pristine™ Hemodialysis catheter. The GlidePath™ Long-Term Hemodialysis Catheter reference device is included for sterilization, shelf-life, packaging, printing of the bifurcation and

ID clamps of the catheter, and kit componentry and associated equivalent material comparisons only.

Performance Data:

The subject device, Pristine™ Long-Term Hemodialysis Catheter, met all of the design verification and validation requirements previously reported for the predicate device, Pristine™ Hemodialysis Catheter (K182443, cleared May 31, 2019). All samples used for final testing of each product attribute were representative of finished products.

For the various design changes, which includes the modified luer geometry change, extension legs process aid material change, and the bifurcation design change, verification testing was performed to the exact same acceptance criteria as K182443 and outlined below:

- Dimensional and Workmanship Analysis: Luers
- Luer Occlusion
- Luer Assembly Tensile
- Leak Decay

For the additional BPV design changes, such as modified packaging change and modified tunneler design, additional verification and validation testing was performed based on Bard's acceptance criteria. It should be noted that the additional verification and validation tests that were completed based on the modifications made for the subject device are outlined below:

- Tunneler (Shaft to Tunneler Tensile)
- Tunneler (Damage after Removal)
- Sterile Barrier Visual Inspection
- Sterile Barrier Integrity (Bubble Leak, Dye Leak)
- Minimum Seal Width
- External Literature Pouch Damage
- Label Legibility
- Tray Cracking
- Component Movement and Damage
- Peel Force Test (Poly to Poly, Poly to Tyvek)

All other original verification and validation testing previously completed for the predicate device remains the same and is unchanged as it relates to the subject Pristine™ Long-Term

Hemodialysis Catheter. The original testing from the predicate Pristine™ Hemodialysis Catheter was previously provided in K182443, which was cleared on May 31, 2019.

Conclusion:

The subject device, the Pristine™ Long-Term Hemodialysis Catheter, meets all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Pristine™ Long-Term Hemodialysis Catheter is therefore substantially equivalent to the legally marketed predicate device, Pristine™ Hemodialysis Catheter.