November 18, 2020

C.R. Bard, Inc.
Joan Bergstrom
Regulatory Affairs Specialist
1625 W. Third Street
Tempe, AZ 85281

Re: K202150
Trade/Device Name: GlidePath™ 7.5F Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device And Accessories
Regulatory Class: Class II
Product Code: MSD
Dated: October 16, 2020
Received: October 19, 2020

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 (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,

for 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)*

K202150

Device Name
GlidePath™ 7.5F Long-Term Hemodialysis Catheter

Indications for Use *(Describe)*
The GlidePath™ 7.5F Long-Term Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access in pediatric, adolescent, and adult patients for hemodialysis, hemoperfusion or apheresis as determined by the prescribing physician. Access is attained via the internal jugular vein, subclavian vein, or femoral vein.

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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GlidePath™ 7.5F 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:	480-597-8425
Fax:	480-449-2546
Contact:	Joan Bergstrom, Regulatory Affairs Specialist
Date	July 31, 2020

Subject Device Name:

Device Trade Name:	GlidePath™ 7.5F 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:

Bard GlidePath™ 10F Long-Term Hemodialysis Catheter (K200627, cleared June 22, 2020)

Device Description:

The GlidePath™ 7.5F Long-Term Hemodialysis Catheter features a dual-lumen shaft with optimized double-D cross-sectional designs providing separate arterial and venous lumens, a molded bifurcation and, extending from the bifurcation, arterial and venous extension legs that connect to an external dialysis machine or blood cleansing device. The arterial (red) luer connector secures to the blood intake on the dialysis machine and the venous (blue) luer connector secures to the blood return line on the dialysis machine. Each extension leg has an atraumatic occlusion clamp which closes access to the lumen. Long-term dialysis catheters are packaged in a tray with legally marketed accessories intended for use during catheter placement. The symmetrical catheter tip contains holes that aid in the distribution of blood flow or aid in over-the-guidewire placement. The symmetrical catheter tip contains holes that aid in the distribution of blood flow or aid in over-the-guidewire placement. The dialysis catheter is offered in various lengths. This line extension of GlidePath™ has been designed with smaller patients in mind and for physicians that may prefer a smaller diameter catheter, so product offerings include smaller lumen diameter and shorter lengths, 8 cm to 19 cm, tip to cuff measurement. Additionally, GlidePath™ 7.5F Long-Term Hemodialysis Catheters have been designed to reach adequate flow rate requirements for pediatric patients or smaller adult patients for whom a physician desires a smaller catheter size.

Attribute	GlidePath™ 7.5F Long-Term Hemodialysis Catheter Product Offerings
Catheter Diameter (F)	7.5
Catheter Shaft Length (cm)	8, 10, 12, 15, 19

Indications for Use of Device:

The GlidePath™ 7.5F Long-Term Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access in pediatric, adolescent, and adult patients for hemodialysis, hemoperfusion or apheresis as determined by the prescribing physician. Access is attained via the internal jugular vein, subclavian vein, or femoral vein.

Comparison to Predicate Device:

The GlidePath™ 7.5F Long-Term Hemodialysis Catheter has the following similarities to the Predicate, Bard GlidePath™ 10F Long-Term Hemodialysis Catheter (K200627, cleared June 22, 2020):

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

Additional pediatric catheter reference device Arrow Pediatric Two-Lumen Hemodialysis Catheter (K984022, cleared May 18, 1999) is included as a lumen size reference for Mechanical Hemolysis, Flow Rate versus Pressure and Catheter Tensile comparisons specifically. There are no outstanding differences between the subject device and the predicate and reference devices.

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate and reference device, their technical 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:

- Catheter Tip (Damage After Flexure)
- Tip Tensile
- Tunneler (Shaft to Tunneler Tensile)
- Catheter Tip Stiffness
- Surface Inspection
- Catheter Insertion Over Split Sheath Introducer
- Assembly Leak Resistance
- Flow Rates
- Catheter Collapse
- Catheter Tensile (Shaft to Bifurcation)
- Catheter Tensile (Extension Leg to Bifurcation)

- Catheter Tensile (Extension Leg to Connector)
- Cuff Securement
- Burst
- Recirculation
- Mechanical Hemolysis
- Catheter Shaft Stiffness
- Catheter Radiopacity
- Thumb Clamps
- Extension Legs (Knitting, Flow)

The results from these tests performed in accordance with standards and FDA guidance, demonstrate that the technical characteristics and performance criteria of the GlidePath™ 7.5F Long-Term Hemodialysis Catheter is substantially equivalent to the predicate and comparable to the reference, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion:

The subject device, the GlidePath™ 7.5F 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 GlidePath™ 7.5F Long-Term Hemodialysis Catheter is therefore substantially equivalent to the legally marketed predicate device, the Bard GlidePath™ 10F Long-Term Hemodialysis Catheter.