June 22, 2020

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

Re: K200627
Trade/Device Name: GlidePath 10F Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: May 21, 2020
Received: May 22, 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,

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)*
K200627

Device Name
GlidePath™ 10F Long-Term Hemodialysis Catheter

Indications for Use *(Describe)*
The GlidePath™ 10F 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. Catheters longer than 22 cm are intended for femoral vein insertion, depending on patient anatomy and size.

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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GlidePath™ 10F 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 June 15, 2020

Subject Device Name:

Device Trade Name:	GlidePath™ 10F 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™ Long-Term Hemodialysis Catheter (K190527, cleared March 5, 2020)

Pediatric Reference Device:

Medcomp Pediatric Ash Split Cath™ XL 10F (K020936, cleared October 11, 2002)

Device Description:

The Glidepath™ 10F 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 connects to the blood intake on the dialysis machine and the venous (blue) luer connector connects 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 dialysis catheters are 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 the smaller lumen diameter, 10 F, and shorter lengths, 10 cm to 23 cm. Additionally, Glidepath™ 10F Long-Term Hemodialysis Catheter has 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™ 10F Long-Term Hemodialysis Catheter Product Offerings
Catheter Diameter (F)	10
Catheter Shaft Length (cm)	10, 12, 15, 19, 23

Indications for Use of Device:

GlidePath™ 10F 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. Catheters longer than 22 cm are intended for femoral vein insertion, depending on patient anatomy and size.

Comparison to Predicate and Reference Devices:

The Glidepath™ 10F Long-Term Hemodialysis Catheter has the same design, materials, and intended use as the Predicate, Bard GlidePath™ Long-Term Hemodialysis Catheter

(K190527, cleared March 5, 2020). Additional Pediatric Reference Device, Medcomp Pediatric Ash Split Cath™ XL 10F (K020936, cleared October 11, 2002) is a performance testing comparator, specifically comparing flow of the subject devices to a pediatric device to demonstrate the substantial equivalence in support of a Pediatric Indication.

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate and reference devices, 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 the same standards and FDA guidance were used for the subjects, references, and predicate device to validate the designs.

The comparative results for pediatric specific characteristics of flow rates, recirculation, and hemolysis also demonstrate that the technical characteristics and performance criteria of the GlidePath™ 10F Long-Term Dialysis Catheter is substantially equivalent to the pediatric reference device Medcomp Pediatric Ash Split Cath™ XL 10F. The testing results show that the minor differences in device characteristics between the subject device, reference device and predicate device do not raise any new questions of safety or effectiveness and that they can perform in a manner equivalent to devices currently on the market for the same intended use and indicated for a similar patient population.

Conclusion:

The subject device, the GlidePath™ 10F Long-Term Dialysis 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™ 10F Long-Term Dialysis Catheter is therefore substantially equivalent to the legally marketed pediatric reference device Medcomp Pediatric Ash Split Cath™ XL 10F and the legally marketed predicate device, the Bard GlidePath™ Long-Term Hemodialysis Catheter.