



June 4, 2021

Bard Peripheral Vascular, Inc.
Joan Bergstrom
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, AZ 85281

Re: K211410
Trade/Device Name: GlidePath™ 13F 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 5, 2021
Received: May 6, 2021

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

Indications for Use

510(k) Number (if known)
K211410

Device Name
GlidePath™ 13F Long-Term Hemodialysis Catheter

Indications for Use (Describe)

The GlidePath™ 13F long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 34 cm are intended for femoral vein insertion.

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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**Special 510(k)
GlidePath™ 13F Long-Term Hemodialysis Catheter**

510(k) Summary

**GlidePath™ 13F 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 May 5, 2021

Subject Device Name:

Device Trade Name: GlidePath™ 13F 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

Review Panel: Gastroenterology/Urology

Predicate Device:

GlidePath™ Long-Term Hemodialysis Catheter (K190527, cleared March 5, 2020)

**Special 510(k)
GlidePath™ 13F Long-Term Hemodialysis Catheter**

Device Description:

The GlidePath™ 13F Long-Term Hemodialysis Catheter is a vascular access device, intended for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy and features a dual-lumen, optimized double-D cross-sectional catheter shaft with a fixed symmetrical tip design. The catheter has separate arterial and venous lumens, a molded bifurcation and, extending from the bifurcation, arterial (red) luer and venous (blue) luer and extension legs which connect to an external dialysis machine or blood cleansing device. Each extension leg has an atraumatic occlusion clamp which closes access to the lumen. The symmetrical catheter tip contains holes that aid in the distribution of blood flow and aid in over-the-guidewire placement. The GlidePath™ 13F Long-Term Hemodialysis Catheters are packaged in a tray with legally marketed accessories intended for use during catheter placement. The device is intended for single patient use only.

Attribute	GlidePath™ 13F Long-Term Hemodialysis Catheter Product Offerings
Catheter Diameter (F)	13
Catheter Shaft Length, Tip to Cuff (cm)	15, 19, 23, 27, 31, 35

Indications for Use of Device:

The GlidePath™ 13F Long-Term Hemodialysis Catheter are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 34 cm are intended for femoral vein insertion.

Comparison to Predicate Device:

The GlidePath™ 13F Long-Term Hemodialysis Catheter has the following similarities to the Predicate, Bard GlidePath™ Long-Term Hemodialysis Catheter (K190527, cleared March 5, 2020):

- Same catheter shaft material
- Same intended use
- Same indications for use
- Same patient target population
- Same operating principle

Special 510(k)
GlidePath™ 13F Long-Term Hemodialysis Catheter

- Same fundamental scientific technology
- Same packaging configurations
- Same sterility assurance level and method of sterilization

The differences of the subject device, GlidePath™ 13F Long-Term Hemodialysis Catheter, from the predicate GlidePath™ (14.5F) Long-Term Hemodialysis Catheter are limited to the catheter shaft diameter and catheter lengths offered.

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, both technical characteristics and performance criteria were evaluated. Using FDA Guidance documents on non-clinical testing of medical devices and internal Risk Assessment procedures, tests for the following characteristics and performance criteria were evaluated for the subject device:

- Catheter Tensile
- Catheter Tip Stiffness
- Catheter Tip Damage after Flexure
- Flow Rate
- Recirculation
- Mechanical Hemolysis
- Catheter Assembly Leak
- Catheter Burst
- Surface Inspection
- Stylet to Luer Tensile
- Stylet Assembly Leak
- Catheter to Tunneler Rod Tensile
- Tunneler Rod Malleability

The results from these tests performed in accordance with standards and FDA guidance, demonstrate that the technical characteristics and performance criteria of the GlidePath™ 13F Long-Term Hemodialysis Catheter is substantially equivalent to the predicate and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Special 510(k)
GlidePath™ 13F Long-Term Hemodialysis Catheter

Conclusion:

The subject device, the GlidePath™ 13F Long-Term Hemodialysis Catheter, met all predetermined acceptance criteria for design verification and validation activities as specified by applicable standards, guidance, test protocols and/or customer inputs. The subject device and the predicate device share the same materials, intended use, indications for use, target patient population, operating principle, fundamental scientific technology, packaging configurations, and sterility assurance level and method of sterilization. Therefore, Bard Peripheral Vascular, Inc. concludes that the subject device GlidePath™ 13F Long-Term Hemodialysis Catheter is substantially equivalent to the legally marketed predicate device, the GlidePath™ Long-Term Hemodialysis Catheter.