March 5, 2020

Bard Access Systems, Inc.
Joan Bergstrom
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, UT 85281

Re: K190527
Trade/Device Name: GlidePath Long-Term Hemodialysis Catheters
HemoStar Long-Term Hemodialysis Catheters
HemoStar XK Long-Term Hemodialysis Catheters
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and accessories
Regulatory Class: II
Product Code: MSD
Dated: June 7, 2019
Received: June 10, 2019

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 tray 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)*
K190527

Device Name
GlidePath™ Long-Term Hemodialysis Catheter
HemoStar™ and HemoStar™ XK Long-Term Hemodialysis Catheters

Indications for Use *(Describe)*
The GlidePath™ 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 40cm are intended for femoral vein insertion.

The HemoStar™ and HemoStar™ XK 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 greater than 40 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.

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GlidePath™ / HemoStar™ / HemoStar™ XK / Long-Term Hemodialysis Catheters
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:

Bard Access Systems (C.R. Bard, Inc.)
605 North 5600 West
Salt Lake City, Utah 84116

Contact: Joan Bergstrom, Regulatory Affairs Specialist
Phone: 480-597-8425
Fax: 480-449-2546
Date of Submission: March 3, 2020
Establishment Registration Number: 3006260740

Subject Device:

Name of Device:	GlidePath™ Long-Term Hemodialysis Catheter HemoStar™ Long-Term Hemodialysis Catheter HemoStar™ XK Long-Term Hemodialysis Catheter
Product Code:	MSD
Classification Name:	**Blood access device and accessories**
Common/Usual Name:	Long-term hemodialysis catheters, or chronic hemodialysis catheters
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5540

Predicate Device:

Name of Device:	HemoGlide™ Star Series Long-Term Hemodialysis Catheter HemoGlide™ Star Series XK Long-Term Dialysis Catheter (K051748, cleared August 12, 2005)
Product Code:	MSD

Classification Name: **Blood access device and accessories**

Regulatory Class: Class II

Regulation Number: 21 CFR 876.5540

Device Description:

The GlidePath™, HemoStar™, and HemoStar™ XK Long-Term Hemodialysis Catheters feature a dual-lumen shaft with 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. Both the staggered and symmetrical catheter tips contain holes that aid in the distribution of blood flow or aid in over-the-guidewire placement. The dialysis catheters are offered in various lengths in straight or Alphacurve™ configurations. Alphacurve™ configurations feature a pre-formed, ~225 º curve. Long-term dialysis catheters are tunneled to provide greater distance between the skin and entry site into the vein and provide a physical barrier to the migration of skin organisms.

The HemoStar™ and HemoStar™ XK Long-Term Dialysis Catheters feature a fixed, staggered distal tip. This tip design is identical to that of the predicate devices, HemoGlide™ Star Series and HemoGlide™ Star Series XK Long-Term Dialysis Catheters, cleared August 12, 2005 under K051748.

The GlidePath™ Long-Term Dialysis Catheters, launched in February 2013, are a modification of the HemoStar™ Long-Term Dialysis Catheters. GlidePath™ catheters feature an optimized catheter shaft extrusion profile and a modified tip which is fixed and symmetrical, allowing for reduced luminal pressure during use. The GlidePath™ catheters also include a preloaded stylet for ease of placement. This accessory was previously cleared under K090101. The changes to the catheter were documented via internal note to file prior to launch in 2013.

Intended Use:

HemoStar™ and HemoStar™ XK Long-Term Hemodialysis Catheters are intended for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Catheters greater than 40 cm are intended for femoral vein insertion.

GlidePath™ Long-Term Hemodialysis Catheters are intended for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Catheters greater than 40 cm are intended for femoral vein insertion.

Indications for Use of Device:

HemoStar™ and HemoStar™ XK 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 greater than 40 cm are intended for femoral vein insertion.

GlidePath™ 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 greater than 40 cm are intended for femoral vein insertion.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject devices is identical to that of the predicate devices, and therefore does not raise any new issues of safety and effectiveness. Therefore, in this regard the subject devices are substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The Bard GlidePath™, HemoStar™, and HemoStar™ XK Long-Term Hemodialysis Catheters are substantially equivalent to the predicate devices, the Bard HemoGlide™ Star Series, and HemoGlide™ Star Series XK Long-Term Hemodialysis Catheter (clearance to market via K051748 on August 12, 2005) in the following ways:

- 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 modifications include the following for HemoStar™, and HemoStar™ XK Long-Term Dialysis Catheters:

- Rebranding from HemoGlide™ Star Series and HemoGlide™ Star Series XK Long-Term Dialysis Catheters to HemoStar™ and HemoStar™ XK Long-Term Dialysis Catheters
- Alphacurve™ (pre-curved) configurations

In 2013, Bard launched the GlidePath™ Long-Term Hemodialysis Catheter with modifications to the HemoStar™ Long-Term Hemodialysis Catheter. These modifications only apply to the GlidePath™ Long-Term Hemodialysis Catheter:

- An optimized extrusion method to improve luminal flow rates was qualified
- A redesigned symmetrical tip
- A tapered ingrowth cuff
- An additional 50cm shaft length (within lengths of the cleared Decathlon Long-Term Hemodialysis Catheter, cleared under K073092)
- A preloaded stylet (cleared under K090101) was added to the kit
- Alphacurve™ (pre-curved) configurations
- The indications for use statement was slightly modified for clarity

Performance Data:

To demonstrate substantial equivalence of the subject devices to the predicate devices, their technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following bench tests were performed on the subject devices:

HemoStar™ and HemoStar XK™ Alphacurve™:

- Guidewire Removal
- Priming Volume
- Shaft Bifurcation Tensile
- Flow Rate

- Shaft Tensile
- Burst Testing
- Kink Testing

GlidePath™ Modifications (including Alphacurve™):

- Shaft Stiffness With and Without Stylet
- Catheter-to-Tunneler Detachment
- Tunneler Tip Bend
- Stylet Removal
- Guidewire removal and Visual Inspection
- Kink Testing
- Catheter Tip Tensile
- Occlusion Simulation against vessel wall – Initial Placement
- Occlusion Simulation against vessel wall – Flow Method
- Tip Stiffness
- Flow and Collapse
- Recirculation – Glass Heart Model
- Radiopacity
- Assembly Tensile
- Assembly Leak Resistance
- Burst
- Cuff Tensile
- Priming Volume
- Introducer Sheath Passage

Conclusions:

The subject devices, the GlidePath™, HemoStar™, and HemoStar™ XK Long-Term Hemodialysis Catheters, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Bard GlidePath™, HemoStar™, and HemoStar™ XK Long-Term Hemodialysis Catheters are substantially equivalent to the legally marketed predicate devices HemoGlide™ Star Series, and HemoGlide™ Star Series XK Long-Term Hemodialysis Catheters.