August 2, 2019

C.R. Bard, Inc.
Kristen Soodak
Senior Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K191143
Trade/Device Name: PowerFlow™ Implantable Apheresis IV Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class: Class II
Product Code: PTD
Dated: July 2, 2019
Received: July 3, 2019

Dear Kristen Soodak:

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. 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,

Sapana Patel -S

for Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*

K191143

Device Name
PowerFlow™ Implantable Apheresis IV Port

Indications for Use *(Describe)*

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, IV fluids, parenteral nutrition solutions, blood and blood products.

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

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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PowerFlow™ Implantable Apheresis I.V. Port

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
605 North 5600 West
Salt Lake City, Utah 84116

Phone: 480-350-6017
Fax: 480-449-2546

Contact Person: Kristen Soodak
Senior Regulatory Affairs Specialist
Date of Preparation: 29 April 2019

Subject Device Name:

Name of Device:	PowerFlow™ Implantable Apheresis IV Port
Common or Usual Name:	Subcutaneous implanted apheresis port
Classification Name:	Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class:	Class 2
Product Code:	PTD
Regulation Number:	21 CFR §880.5965

Predicate Device:

Name of Device:	PowerFlow™ Implantable Apheresis IV Port
Common or Usual Name:	Subcutaneous implanted apheresis port
Classification Name:	Subcutaneous, implanted, intravascular infusion port and catheter
Premarket Notification:	K163001
Regulatory Class:	Class 2
Product Code:	PTD
Regulation Number:	21 CFR §880.5965

Device Description:

PowerFlow™ Implantable Apheresis IV Port

The PowerFlow™ Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex™ Catheter is designed to provide repeated access to the vascular system without the need for repeated venipuncture or the daily care of an external catheter. The PowerFlow™ Implantable Apheresis IV Port is a low profile totally implantable, angled access titanium port-based design and is accessed through an angled opening which consists of a funnel shaped entrance designed to guide the peripheral intravenous (P.I.V.) access needle and catheter into the subject device. The PowerFlow™ Implantable Apheresis IV Port comes with a number of kit components to aid in the implantation procedure and/or access of the device once implanted. The PowerFlow™ Implantable Apheresis IV Port and necessary kit components are provided sterile (EtO).

The overall implanted system consists of three primary components: the port body with a silicone layered septum, an attachable radiopaque polyurethane catheter, and a catheter lock which secures the catheter to the port body stem. The method of implantation and access of the subject PowerFlow™ Implantable Apheresis IV Port is the exact same as the predicate PowerFlow™ Implantable Apheresis IV Port device. After the implanted device has been identified and access is prepped per institutional policy, the user palpates the uniquely shaped angled entry funnel. Once the funnel is palpated, providing the location of the introducer needle access path, the 14 or 16Ga introducer needle is inserted into the funnel. After the Introducer Needle Stop is reached, the Introducer Needle is pulled back slightly and the P.I.V. Catheter is advanced forward. The P.I.V. Catheter is then advanced through the silicone layered septum and the Introducer Needle is removed. After needle removal, the P.I.V. Catheter is attached to the appropriate extension set and secured for the necessary infusion or withdrawal procedure.

The PowerFlow™ Implantable Apheresis IV Port can be used for routine vascular access infusion or withdrawal using a BD Insyte™ Autoguard™ Shielded IV Catheter. For power injection infusion procedures, the subject device can be accessed with a power injection rated IV catheter to create a power-injectable system.

Intended Use:

The PowerFlow™ Implantable Apheresis IV Port is intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.

Indications for Use of Device:

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, IV fluids, parenteral nutrition solutions, blood and blood products.

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Technological Comparison to Predicate Devices:

The PowerFlow™ Implantable Apheresis IV Port is identical to the predicate device, the PowerFlow™ Implantable Apheresis IV Port (clearance to market via K163001 on April 17, 2017) in the following ways:

- Same intended use
- Same indications for use
- Same fundamental scientific technology
- Same operating principle and method of action
- Same packaging configuration
- Same sterility assurance level and method of sterilization
- Same material type (Ti-6AL-4V)

The following change has been made between the subject device and the predicate device:

- The port base incorporates an alternative titanium formulation (Ti-6AL-4V Type 1 MIM per ASTM F2885-17) and manufacturing method (Metal Injection Molding). The predicate device used Ti-6AL-4V-ELI Grade 23 per ASTM F136 and machining as the manufacturing method.

Performance Tests:

To demonstrate substantial equivalence of the subject device to the predicate device, its 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 verification tests were performed on the subject device:

- Port Subassembly Radiopacity
- Corrosion Resistance

- Silicone Boot Retention
- Stem Tensile Strength
- Stem-Catheter Connection Air Leak
- Valve Life

The results demonstrate that the subject device met all pre-determined acceptance criteria and that it performs equivalently to the predicate device.

Cytotoxicity was conducted on the subject device, and chemical characterization testing was conducted on the predicate and subject device to confirm toxicological equivalence. Additionally, testing conducted on a component made of the same MIM titanium material was leveraged. This testing included Chemical Characterization, Cytotoxicity, Sensitization, Intracutaneous irritation, Acute systemic toxicity, Genotoxicity (Ames), Genotoxicity (Chromosomal Aberrations), Implantation – 13 week intramuscular, and Implantation – 13 week bone. This information demonstrates that the subject device is biocompatible and does not elicit any substances at levels of concern as a result of this change.

The subject device is sterilized using ethylene oxide and was adopted into the same validated sterilization cycle as the predicate device. Endotoxin (LAL) and EO residual testing will be routinely performed.

Summary of Substantial Equivalence:

The subject device met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Therefore, the subject device is considered substantially equivalent to the predicate device.