October 17, 2019

Bard Peripheral Vascular
Kulveen Dhatt
Senior Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, AZ 85281

Re: K192239
Trade/Device Name: WavelinQ EndoAVF System
Regulation Number: 21 CFR 870.1252
Regulation Name: Percutaneous Catheter for Creation Of An Arteriovenous Fistula
Regulatory Class: Class II
Product Code: PQK
Dated: August 16, 2019
Received: August 19, 2019

Dear Ms. Dhatt:

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,

Carmen Gacchina Johnson
Acting Assistant Director
DHT2B: Division of Circulatory Support, Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K192239

Device Name
WavelinQ EndoAVF System

Indications for Use *(Describe)*
The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

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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WavelinQ™ EndoAVF System

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:	480-379-2875
Fax:	480-449-2546
Contact:	Kulveen Dhatt, Senior Regulatory Affairs Specialist
Date:	August 16, 2019

Subject Device Name:

Device Trade Name:	WavelinQ™ EndoAVF System
Common or Usual Name:	Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access
Classification Name:	Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access
Product Code:	PQK
Regulatory Class:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1252

Predicate Device:

Device Trade Name:	WavelinQ™ 4F EndoAVF System
510(k) Number:	K182796
Common or Usual Name:	Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access

Classification Name:	Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access
Product Code:	PQK
Regulatory Class:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1252

Device Description:

The WavelinQ™ EndoAVF System consists of two single-use disposable magnetic catheters: a venous catheter and an arterial catheter. The venous catheter contains an array of magnets positioned on either side of a radiofrequency (RF) cutting electrode contained within an isolative housing. The arterial catheter contains a matching array of magnets positioned on either side of an electrode "backstop". The backstop serves as a mechanical stop for the cutting electrode to contact following the creation of the AVF. The magnets in the two catheters serve to align and appose the arterial backstop of the arterial catheter with the RF electrode of the venous catheter when positioned in the target AVF location. Radiofrequency energy can then be delivered through the electrode for cutting tissue and AVF creation.

The arterial and venous catheters are both comprised of braid reinforced Pebax catheter shafts. These shafts provide flexibility for device delivery and torquability to aid in rotational alignment and positioning. Both catheters include a soft, radiopaque, rapid exchange style Pebax tip for atraumatic device navigation with radiographic visibility. These tips allow the catheters to track over a standard guide wire 0.014" or smaller. The catheters include a handle/hub to facilitate device delivery, positioning and alignment.

Indications for Use of Device:

The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

Technological comparison to Predicate Device:

The subject WavelinQ™ EndoAVF System has the following similarities to the WavelinQ™ 4F EndoAVF System predicate device (K182796 – cleared on February 6, 2018): 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, same performance bench testing with same acceptance criteria, same biocompatibility requirements, same packaging configurations, and same materials.

The WavelinQ™ EndoAVF System includes minor design modifications when compared to the WavelinQ™ 4F EndoAVF System predicate device. The WavelinQ™ EndoAVF System includes one additional radiopaque rotational indicator to both the venous and arterial catheters and the addition of 24 magnets each to both the arterial and venous catheters. The minor design modifications have been verified and validated through appropriate non clinical performance data. There are no changes with respect to manufacturing, materials and their processing compared to the predicate WavelinQ™ 4F EndoAVF System. Magnet Array Force Coaptation Testing and S-Turn Tortuosity Coaptation and Alignment Comparison Testing were introduced as a verification tests in order to compare the subject device to the predicate device and confirm that minor modifications of the WavelinQ™ EndoAVF System maintain or exceed performance requirements previously established with the predicate WavelinQ™ 4F EndoAVF System.

In order to address the performance requirements previously validated by end users which are potentially impacted by the minor design modifications, repeat validation testing was performed on the subject WavelinQ™ EndoAVF System to confirm design outputs continue to satisfy the design inputs and user needs. The repeat design validation provides confirmation that design outputs satisfy those design inputs that may not otherwise be evaluated through design verification testing.

Performance Data:

Non Clinical Performance Data:

To demonstrate that the subject device WavelinQ™ EndoAVF System is as safe and effective as the predicate device WavelinQ™ 4F EndoAVF System, the technological characteristics and performance criteria were evaluated. Using internal risk assessment procedures, tests of the following characteristics and performance criteria were performed on the subject device:

- Electrical Safety per IEC 60601
- Electromagnetic Compatibility (EMC) Testing
- Design Validation – Cadaver Study
- Magnet Array Force Coaptation Testing
- S-Turn Tortuosity Coaptation and Alignment Comparison Testing

Conclusions:

The subject device, WavelinQ™ EndoAVF System, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The subject device and the predicate device share the same characteristics: intended use, indications for use, target population, conditions for use, and fundamental scientific technology. Therefore, Bard Peripheral Vascular, Inc. concludes that the subject device WavelinQ™ EndoAVF System is substantially equivalent to the legally marketed predicate device WavelinQ™ 4F EndoAVF System.