February 6, 2019

C. R. Bard, Inc.
Kulveen Dhatt
Regulatory Affairs Specialist II
1625 West 3rd Street
Tempe, AZ 85281

Re: K182796
Trade/Device Name: WavelinQ 4F EndoAVF System
Regulation Number: 21 CFR 870.1252
Regulation Name: Percutaneous Catheter for Creation of an Arteriovenous Fistula for Hemodialysis Access
Regulatory Class: Class II
Product Code: PQK
Dated: January 4, 2019
Received: January 7, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182796

Device Name
WavelinQ 4F EndoAVF System

Indications for Use *(Describe)*
The WavelinQ 4F 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™ 4F EndoAVF System**

**Traditional 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: | January 7, 2019 |


**Subject Device Name:**

| | |
|---|---|
| Device Trade Name: | WavelinQ™ 4F 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: | everlinQ® endoAVF System (DEN160006) |
| 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™ 4F 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 subject device 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™ 4F EndoAVF System has the following similarities to the everlinQ® endoAVF System predicate device (DEN160006 – granted marketing authorization on June 22, 2018): same intended use, similar indications for use, same target population, same operating principle, same fundamental scientific technology, same sterility assurance level and method of sterilization, similar performance bench testing with similar acceptance criteria, same biocompatibility testing performed, similar packaging configurations, and comparable safety and performance data from clinical studies.

The WavelinQ™ 4F EndoAVF System includes minor differences when compared to the everlinQ® endoAVF System predicate device that give the subject device a lower, 4 French (Fr), profile allowing additional access site option (venous wrist access). In addition to the lower profile design with venous wrist access capabilities, the WavelinQ™ 4F EndoAVF System includes an expanded indication to include radial artery and radial vein in addition to ulnar artery and ulnar vein and removal of the separation distance between the artery and vein at the fistula creation site, antiparallel catheter configuration, modified geometry of catheter components, minor material differences, and addition of radiopaque rotational indicators to the venous and arterial catheters. The minor differences have been verified and validated through appropriate non clinical and clinical performance data.

**Performance Data:**

*Non Clinical Performance Data:*

To demonstrate that the subject device WavelinQ™ 4F EndoAVF System is substantially equivalent to the predicate device everlinQ® 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:

- Visual Inspection
- Simulated Use
- Electrode Deployment/Height
- Catheter Alignment
- Energy Delivery
- Electrode Durability
- Tensile Strength
- Torque Strength
- Corrosion Resistance
- Catheter Lubricity

- Electrical Safety per IEC 60601q
- Mechanical Integrity
- Assembly, Component and Material Inspection
- Shelf Life
- Package Performance
- Sterility & Endotoxin
- Biocompatibility per ISO 10993

*Clinical Performance Data:*

A Global Analysis of the WavelinQ™ 4F EndoAVF System was conducted in order to confirm that the WavelinQ™ 4F EndoAVF System is a substantially equivalent treatment option for patients in need of hemodialysis access. Data from three sources (EASE Study, EASE-2 Study, and the EU Post-Market Study) was collected and analyzed. Data were analyzed individually by study and in the aggregate with pooled data through six months. The study population consisted of all available clinical study subjects treated with the WavelinQ™ 4F EndoAVF System from the sponsor's global clinical studies, and resulted in a population of combined subjects from the EASE Study, the EASE-2 Study, and the 4F cohort of the EU Post-Market Study. There were Ninety-one (91) total subjects in the global analysis at eight (8) total investigational sites in Paraguay (Ease and EASE-2) and Germany and the United Kingdom (EU Post-Market Study). Subjects eligible to be enrolled in this study were adult male and non-pregnant females with kidney failure and the target vein and artery were within parameters that could be treated in accordance with the IFU. Primary effectiveness endpoints were defined as the proportion of subjects with the following: procedural success, time to cannulation, cannulation success, primary patency, modified primary patency, assisted patency, secondary patency, functional patency, and functional cannulation. Primary safety endpoints were defined as the proportion of subjects with the following: significant events, serious adverse events (SAEs), device-related SAEs, procedure-related SAEs, closure device-related SAEs, and coil-related SAEs.

At 6 months, 46/55 eligible subjects completed follow-up within the window, while 36 subjects were not eligible. Not eligible subjects are not eligible for the analysis because they have exited the study, or they have not reached the end of the follow-up visit window and are not yet exited or determined to have missed the visit. Subjects were withdrawn when they exited a study due to an unsuccessful index procedure, abandonment or failure of the endoAVF, death, exit due to adverse event, investigator decision, or loss to follow-up.

Procedural success, defined as the successful creation of an endoAVF with blood flow confirmed intraoperatively with fistulography or postoperative duplex ultrasonography, was achieved in 96.7% (88/91) of the Pooled Population. Cannulation Success was defined as 2-needle access and hemodialysis through the endoAVF. Cannulation Success was calculated for all subjects and for the subset of those who were on dialysis at the time of enrollment. Using Kaplan-Meier (K-M) point estimates, Cannulation Success was achieved through 6 months (210 days) in 74.2% ± 7.4% of all subjects and in 86.0% ± 6.3% of subjects in the Dialysis Subset.. The median time to successful cannulation was 1.3 months after creation of the endoAVF. Primary, Assisted Primary, and Secondary patency were defined according to the Society of Vascular Surgery (SVS) reporting standards. Rates were determined using the K-M point estimates at month 6. Primary Patency was achieved in 82.3% ± 4.9% at 6 months. Corresponding rates for Assisted Primary and Secondary Patency were each 86.6% ± 4.5% (K-M estimates and SE through 210 days). As an additional measure of patency, a modification of the SVS-defined Primary Patency rate was used. This measure, Modified Primary Patency, was identical to Primary Patency except that loss was also triggered by reinterventions not directly related to the access circuit; namely coiling or vessel ligation of venous outflow tributaries to encourage flow into the superficial, more easily accessible veins of the upper arm.[1] Modified Primary Patency was achieved in 81.0% ±5.0% at 6 months in the Pooled Population. Functional Cannulation rates were assessed utilizing the K-M estimates at 6 months where time 0 was the date of the index procedure, irrespective of whether the subject was on dialysis at that time. In all subjects, including those subjects enrolled pre-dialysis who did not receive dialysis during study follow-up, Functional Cannulation was achieved in 66.1% ± 8.1% of the population at 6 months. Functional Cannulation was achieved in 77.2% ± 7.8% of the Dialysis Subset at 6 months. The median Time to Function Cannulation was 1.6 months after the index procedure.

Adverse events were site-reported and reviewed by an independent Medical Monitor and the Clinical Events Committee (CEC). The Investigators reported all events that, in their opinion, were related to the device, to the index procedure, to other subsequent procedures that were in any way related to the index procedure (e.g. reinterventions), or to the access circuit. As well, all deaths were reported. In total, 11.0% (10/91) of the 4 Fr endoAVF subjects experienced a Significant Event. These 10 subjects experienced 11 Significant Events including access circuit stenosis, occlusions and/or thromboses, as well as one subject with abandonment of the

[1] Loss of Modified Primary Patency was not triggered by coiling or surgical outflow vein ligation performed during the index procedure. Only secondary interventions were included in the definition of Modified Primary Patency.

endoAVF after a cannulation induced brachial artery injury. There were no device-related serious adverse events (SAEs) and there were three (3_ procedure-related SAEs reported in 3.3% (3/91) of the Pooled Population during the study. None of the serious adverse events were related to the use of closure devices or coil embolizations. The results of the study indicate that the design of WavelinQ™ 4F EndoAVF System allowed for adequate creation of an endoAVF with blood flow confirmed intraoperatively fistulography or postoperative duplex ultrasonography and cannulation success.

The results from these performance data demonstrate that the technological characteristics and performance criteria of the WavelinQ™ 4F EndoAVF System are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

**Conclusions:**

The subject device, WavelinQ™ 4F 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 or similar 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™ 4F EndoAVF System is substantially equivalent to the legally marketed predicate device everlinQ® endoAVF System.