October 17, 2022

C.R. Bard, Inc.
Jakob Wells
Senior Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K222793
Trade/Device Name: WavelinQ™ Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 15, 2022
Received: September 16, 2022

Dear Jakob Wells:

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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222793

Device Name
WavelinQ™ Generator

Indications for Use *(Describe)*
The WavelinQ™ Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**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 summary of the information upon which substantial equivalence determination is based is as follows:

**1. Submitter Information:**


| | |
|---|---|
| Applicant: | Bard Peripheral Vascular, Inc.<br>1625 West 3rd Street<br>Tempe, Arizona 85281 |
| Phone: | *602-830-5382* |
| Contact: | Jakob Wells, Senior Regulatory Affairs Specialist |
| Alternate Contact: | Kulveen Dhatt, Senior Regulatory Affairs Manager |
| Date: | September 15, 2022 |


**2. Subject Device:**

| | |
|---|---|
| Device Trade Name: | **WavelinQ™ Generator** |
| Common or Usual Name: | Electrosurgical, cutting & coagulation & accessories |
| Classification: | Class II |
| Classification Name: | Electrosurgical, cutting & coagulation & accessories (Product code GEI) |
| Review Panel: | General and Plastic Surgery |
| Regulation Number: | 21 CFR 878.4400 |

**3. Predicate Device:**

The predicate device is the ESU-1 Electrosurgical Generator (K162656) cleared November 10, 2016.

**4. Device Description:**

The WavelinQ™ Generator is a high frequency isolated generator that utilizes electrical current to deliver radiofrequency (RF) energy to the catheter electrode for formation of a

vascular fistula. The generator offers a receptacle for a monopolar handpiece. The WavelinQ™ Generator is intended to be used with the currently marketed and cleared device WavelinQ™ EndoAVF System (K192239). The generator has one setting (AV1) equivalent to the mode (Cut T, 60W, 0.7s) of the predicate device, ESU-1 Electrosurgical Generator, that is used during the WavelinQ™ EndoAVF System procedure. This mode is set to deliver energy at 60 Watts for 0.7 seconds. The generator has a return electrode contact, for use with a split ground pad, and quality monitoring system (NEM) to reduce the risk of patient burns at the return electrode site. The pad-sensing feature allows the user to use only a split return electrode, also referred to as a split ground pad.

The device consists of a generator and power cord and is packaged with a User's Guide in a cardboard shipping box with protective foam inserts. The main device components are a front panel containing the power button, LED numeric display, alarm and return electrode indicator lights, and connector ports for accessories, a back panel consisting of volume controls, a power cord outlet and fuse, and internal components (printed circuit boards, speakers, cabling).

**5. Indications for Use of Device:**

The WavelinQ™ Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

**6. Technological Comparison to Predicate Devices:**

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended use
- Indications for use
- Product Classification
- Fundamental scientific technology
- Operating principle
- Packaging materials

The subject device is a modification of the predicate device with the following differences:

- ESU2 circuitry components of the device board architecture require a different power supply as compared to the predicate to allow for a singular mode and streamlined display to simplify user interface
    - ESU2 does not have adjustable power delivery settings and only allows for RF energy delivery at the level required for the WavelinQ™ EndoAVF System (setting AV1)
    - ESU2 only contains connection ports used as part of the WavelinQ™ EndoAVF System procedure and only has accessible ports used for connection of an electrosurgical pencil and a grounding pad
- Addition of new specifications to align with BD design control requirements and electrical safety testing
- Decrease maximum validated power output.
- Addition of the ability for BD service personnel to access activation statistics for historic activations
- ESU2 physical dimensions are smaller and more lightweight

**7. Performance Testing Summary:**

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessment procedures, the following non-clinical tests were performed:

**Verification Test Activities:**

- Electrical Testing
    - Electrical Safety Testing
    - EMC Testing
- Inspection Testing
- Mechanical Testing

**Validation Test Activities:**

- FPGA validation
    - Display Board
    - Main Board

- Reliability validation
- Ship testing
- System functionality testing
- Usability testing
- Cleaning Testing
- Low Level Disinfection Testing

Design verification and validation testing were performed with consideration to the following FDA guidance documents and recognized standards:

- "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997
- "Applying Human Factors and Usability Engineering to Medical Devices", Dated February 2016.
- "General Principles of Software Validation; Final Guidance for Industry and FDA Staff", dated January 11, 2002.
- "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" dated March 2020.
- IEC 60601-1:2005, AMD1:2012, AMD2:2020
- IEC 60601-1-2:2014
- IEC 60601-2-2:2017
- IEC 62366-1:2015

The results demonstrate that the technological characteristics and performance criteria of the WavelinQ™ Generator is comparable to the predicate device and that it performs as safely and as effectively as the legally marketed predicate device.

**8. Conclusion:**

The WavelinQ™ Generator is substantially equivalent to the legally marketed predicate device, the ESU-1 Electrosurgical Generator (K162656).