November 7, 2019

Bard Peripheral Vascular, Inc.
Meghan Mckelvey
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K192948
Trade/Device Name: EleVation Breast Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 17, 2019
Received: October 18, 2019

Dear Meghan Mckelvey:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192948

Device Name
EleVation™ Breast Biopsy System

Indications for Use *(Describe)*
The EleVation™ Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities.

The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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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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. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-350-6153
Fax:	480-449-2546
Contact:	Meghan McKelvey, Regulatory Affairs Specialist
Date:	October 18, 2019

2. Subject Device:

Device Trade Name:	**ELEVATION™ Breast Biopsy System**
Classification Name:	Instrument, Biopsy (Product Code KNW)
Review Panel:	Gastroenterology/Urology
Regulation Number:	21 CFR 876.1075

3. Predicate Device:

FINESSE® Ultra Breast Biopsy System (K103359; cleared December 27, 2010)

4. Device Description:

The ELEVATION™ Breast Biopsy System is a handheld, self-contained, single insertion, multiple sample vacuum-assisted biopsy device and is intended to be used with ultrasound guidance. The device can obtain and store multiple samples with a single insertion probe. The components of the system are designed to operate safely when used together for diagnostic sampling during a breast biopsy procedure. The device consists of a battery-powered, reusable driver and a disposable probe with a sample container.

5. Indications for Use of Device:

The ELEVATION™ Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis for breast abnormalities. The instrument is intended

to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g. malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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
- Performance Characteristics
- Target Population
- Fundamental Scientific Technology
- Operating Principle (Mechanism of Action)
- Patient Contacting Materials
- Sterility Assurance Level and Method of Sterilization

The subject device and the predicate device are different in the following manner:

- Optimized Tissue Cutting and Transport Method
- Echogenic Markings on Needle
- TriConcave™ Needle Tip
- Driver Packaging Configuration
- Software Modifications

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 assessments procedures, the following non-clinical tests were performed:

- Sampling Reliability
- Prime/Pierce Reliability
- System Lifetime Reliability
- Driver Components Reliability
- Needle Requirements
  -Gauge size and length
  -Penetration Force
  -Sample Notch Length
  -Penetration Force
- Probe Torque
- Probe Bending
- Tissue Sample Quality
- Tensile
- Driver Reprocessing
- Driver Packaging Validation
- Software Validation

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

8. Conclusion:

The ELEVATION™ Breast Biopsy System is substantially equivalent to the legally marketed predicate device, the FINESSE® Ultra Breast Biopsy System (K103359).