



July 15, 2021

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

Re: K211933

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: June 21, 2021
Received: June 22, 2021

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

Indications for Use

510(k) Number (if known)
K211933

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 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.

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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510(k) Summary (K211933)

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: 602-830-5063

Fax: 312-949-0436

Contact: Meghan McKelvey, Senior Regulatory Affairs Specialist

Date: July 14, 2021

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:

ELEVATION™ Breast Biopsy System (K192948; cleared November 7, 2019)

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
- Shelf-Life
- Packaging Configuration

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

- Software Modifications (Transportation Indicator and Enhanced Logging Capabilities)
- Needle Tip Modification (Needle Tip Dimensional Improvement and Venting Hole Change)
- Addition of Optional Accessories (Introducer Stylet, Half-Notch Support Cannula, Additional Sample Container)

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:

- Software Validation
- Penetration Force Testing
- Tensile Testing
- Prime/Pierce Testing
- Reliability Testing
- Sample Mass Testing

The results demonstrate that the technological characteristics and performance criteria of the modified 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 modified ELEVATION™ Breast Biopsy System is substantially equivalent to the legally marketed predicate device, the ELEVATION™ Breast Biopsy System (K192948).