July 10, 2025

Bard Peripheral Vascular, Inc.
Rachel Lapoint
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, Arizona 85281

Re: K250032
Trade/Device Name: Marquee™ Disposable Core Biopsy Instruments and Kits (MQ1210, MQ1213, MQ1410, MQ1413, MQ1416, MQ1610, MQ1616, MQ1620, MQ1810, MQ1816, MQ1820, MQ1825, MQ2010, MQ2016, MQ2020, MQK1210, MQK1213, MQK1410, MQK1413, MQK1416, MQK1610, MQK1616, MQK1620, MQK1810, MQK1816, MQK1820, MQK1825, MQK2010, MQK2016, MQK2020)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 13, 2025
Received: June 13, 2025

Dear Rachel Lapoint:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Carr -S

Jessica Carr, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250032

Device Name

Marquee™ Disposable Core Biopsy Instruments and Kits (MQ1210, MQ1213, MQ1410, MQ1413, MQ1416, MQ1610, MQ1616, MQ1620, MQ1810, MQ1816, MQ1820, MQ1825, MQ2010, MQ2016, MQ2020, MQK1210, MQK1213, MQK1410, MQK1413, MQK1416, MQK1610, MQK1616, MQK1620, MQK1810, MQK1816, MQK1820, MQK1825, MQK2010, MQK2016, MQK2020)

Indications for Use *(Describe)*

The Marquee™ Disposable Core Biopsy Instrument and Kit are intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

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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Marquee™ Disposable Core Biopsy Instrument and Instrument Kit

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 substantial equivalence determination is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	(602) 830-5273
Contact Person:	Rachel LaPoint, Regulatory Affairs Specialist
Date of Submission:	July 10, 2025

Subject Device Name:

Device Trade Name:	**Marquee™ Disposable Core Biopsy Instrument and Instrument Kit**
Common or Usual Name:	Instrument, Biopsy (Product Code: KNW)
Classification:	Class II
Classification Name:	Gastroenterology-Urology Biopsy Instrument
Review Panel:	Gastroenterology / Urology
Regulation Number:	21 CFR 876.1075

Predicate Devices:

Bard® Monopty® Disposable Core Biopsy Instrument (K133948, cleared February 21, 2014)

Bard® Mission® Disposable Core Biopsy Instrument and Instrument Kit (K171953, cleared September 14, 2017)

Device Description:

The Marquee™ Disposable Core Biopsy Instrument and Instrument Kit is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The coaxial cannula release is color coded according to the various gauge sizes, e.g., yellow = 20 gauge, pink = 18 gauge, purple = 16 gauge, green = 14 gauge, and light blue = 12 gauge.

The Marquee™ Disposable Core Biopsy Instrument is available as a biopsy instrument only and as a kit, which includes the Marquee™ Disposable Core Biopsy Instrument and compatible Disposable Coaxial Biopsy Needle.

Indications for Use:

The Marquee™ Disposable Core Biopsy Instrument and Kit are intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Technological Comparison to the Predicate Device:

The technological characteristics of the subject device Marquee™ Disposable Core Biopsy Instrument and Instrument Kit are the same or similar as those of the predicate devices, Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Mission® Disposable Core Biopsy Instrument and Instrument Kit:

- Same intended use
- Similar Indications for Use
- Same patient population
- Same principle of operation
- Same duration of use
- Similar device dimensions and materials
- Same sterility assurance level and method of sterilization
- Similar packaging configuration

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

- New labeling with the same intended use and modifications to the Indications for Use Statement
- Change in design (including patient/use interface, needle length, sample notch length, penetration depth)
- Material changes including addition of colorants
- Additional performance specifications
- Addition of Convenience Kit

Biocompatibility:

Per ISO 10993-1:2018, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.” The following biocompatibility tests were successfully

performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute System Toxicity
- Material Mediated Pyrogenicity

The results of biocompatibility testing demonstrate that the subject device Marquee™ is considered biocompatible for its intended use.

Performance Data:

To demonstrate that the subject device Marquee™ is as safe and as effective as the predicate device, its technological characteristics and performance criteria were evaluated.

The following in vitro tests were performed on the subject device:

- Number of Samples
- Penetration Depths
- Stylet / Cannula to Handle Tensile Strength
- Coaxial Stylet to Hub Tensile Strength
- Corresponding Working Needle Length and Cutting Cannula/Coaxial Cannula OD
- Safety
- Reliability
- Integrity of the Sterile Barrier
- Performance After Ship Testing
- Needle Protection After Shipping and Storage
- Shelf Life

Additionally, ex-vivo testing was conducted on porcine tissue to determine sample quality using 12G, 14G, and 20G models of the Marquee™.

A systematic literature review was conducted to support the addition of the breast biopsy indication with peer-reviewed published literature.

Conclusion:

Comparison of technological specifications and performance test data demonstrated that the subject device, the Marquee™ Disposable Core Biopsy Instrument and Instrument Kit, is substantially equivalent to the legally marketed predicate devices for the requested indications for use.