August 14, 2026

Bard Peripheral Vascular, Inc.
Jakob Wells
Regulatory Affairs Manager
1625 W. 3rd St.
Tempe, Arizona 85281

Re: K262571
Trade/Device Name: EnCor EnCompass™ Breast Biopsy and Tissue Removal System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 24, 2026
Received: July 24, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K262571

Device Name
EnCor EnCompass™ Breast Biopsy and Tissue Removal System

Indications for Use *(Describe)*
The EnCor EnCompass™ Breast Biopsy and Tissue Removal System is indicated to acquire breast tissue for histologic examination with partial or complete removal of the abnormality.

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.

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EnCor EnCompass™ Breast Biopsy and Tissue Removal System

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:	(602) 830-5382
Contact Person:	Jakob Wells, Regulatory Manager
Date of Submission:	July 24, 2026

Subject Device:

Name of Device:	EnCor EnCompass™ Breast Biopsy and Tissue Removal System
Common or Usual Name:	Instrument, Biopsy (Product Code: KNW)
Classification Panel:	General & Plastic Surgery
Regulatory Class:	II
Regulation Number:	876.1075

Predicate Device:

EnCor EnCompass™ Breast Biopsy and Tissue Removal System (K252681, cleared on December 12th, 2025)

Device Description:

The subject device, the EnCor EnCompass™ Breast Biopsy and Tissue Removal System, is a console-based vacuum-assisted breast biopsy device. It is intended to obtain breast tissue samples for diagnostic or histologic analysis and may be used under Ultrasound, Stereotactic, or MR imaging guidance. The system consists of a console, handheld driver, foot switch, biopsy probes, canister liner bags, MRI extension tubing, a stereotactic adapter, MRI introducer sets, and spare sample containers. Replacement parts and components of the console, driver, and foot switch that are also sold separately include a reusable vacuum canister, exhaust filter, driver extension cable, foot switch cable, and power cable.

The EnCor EnCompass™ Breast Biopsy and Tissue Removal System consists of multiple devices that are intended to be used together to obtain breast tissue samples. This includes the EnCor EnCompass™ Console, EnCor EnCompass™ Driver, and EnCor EnCompass™ Foot Switch. The console, driver, and foot switch are designed to provide a user interface and to accept inputs used for specific procedures. The console contains a vacuum system and touchscreen monitor. The driver contains multiple buttons to control procedure functionality and is compatible for use with Ultrasound, Stereotactic, and Magnetic Resonance Imaging (MRI) procedures. The foot switch also contains buttons and a pedal to control procedure functionality and has both wired and wireless connectivity options. They are intended to be used with EnCor EnCompass™ Probes, Canister Liner Bags, MRI Extension Tubing, VisiLoc™ MRI Introducer Sets, and Stereotactic Adapter, which are sold separately. The Probes are the Applied Part of the EnCor EnCompass™ Breast Biopsy and Tissue Removal System.

The EnCor EnCompass™ Probe contains a tubular cutter for tissue acquisition and either a sharp trocar tip at the distal end for insertion or a blunt tip at the distal end for use in areas with sensitive structures. A detachable tissue collection chamber is located on the proximal end of the device. The tissue collection chamber incorporates both a suction line for acquisition and transport of tissue samples and a saline line for optional lavage functionality. A Y-valve luer lock is provided for introducing anesthetic to the biopsy site. Compatible breast tissue markers which are sold and packaged separately may be inserted through the proximal end of the device.

The integrated tubing cassette provides vacuum to an EnCor EnCompass™ Probe during a biopsy procedure.

The EnCor EnCompass™ Probe's sample container collects samples as they are acquired and transported during the biopsy procedure. The basket allows for drainage of fluid that is acquired during sampling, vacuuming, and lavaging of the cavity. The basket allows visualization of the samples during and after the procedure and is detachable for sample retrieval post procedure.

The marker adapter allows for marker placement using a marker deployment device through the back of the probe.

The EnCor EnCompass™ Canister Liner Bag collects fluid waste generated during the procedure.

The EnCor EnCompass™ Stereotactic Adapter provides a mechanical interface between the combined EnCor EnCompass™ Driver and EnCor EnCompass™ Probe and the stereotactic biopsy table. The EnCor EnCompass™ Stereotactic Adapter is reusable and affixes directly to the EnCor EnCompass™ Probe with a T-shape fastener and two pins and the EnCor EnCompass™ Driver with rear sliding latches.

Indications for Use:

The EnCor EnCompass™ Breast Biopsy and Tissue Removal System is indicated to acquire breast tissue for histologic examination with partial or complete removal of the abnormality.

Technological Comparison to Predicate Device:

The EnCor EnCompass™ Breast Biopsy and Tissue Removal System has the following similarities to the predicate device (K252681, cleared on December 12th, 2025).

- Same intended use
- Same indications for use
- Same target patient population
- Same principle of operation
- Same fundamental scientific technology
- Same operating principle (mode of action)
- Same sterility level and method of sterilization
- Same packaging configuration
- Same materials
- Same wireless technology

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

- Software modifications

Performance Data:

To demonstrate substantial equivalence of the subject device, the EnCor EnCompass™ Breast Biopsy and Tissue Removal System, to the predicate device, both technological characteristics and performance criteria were evaluated. Testing was conducted based on recommendations in the following FDA Guidance Documents on recognized consensus standards, and internal risk assessment procedures:

- IEC 62304
- ISO 14971

The following tests were performed:

- Software Design Verification and Validation
- Probe Type and Size Reliability Testing

The results from these tests demonstrate that the technological characteristics and performance criteria of the EnCor EnCompass™ Breast Biopsy and Tissue Removal System are comparable to the predicate device, that it can perform in a manner equivalent to devices currently on the

market for the same intended use, and that there are no concerns of safety or effectiveness related to the changes from the predicate device.

Conclusions:

The subject device, the modified EnCor EnCompass™ Breast Biopsy and Tissue Removal System, is substantially equivalent to the legally marketed predicate device, EnCor EnCompass™ Breast Biopsy and Tissue Removal System.