



December 12, 2025

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

Re: K252681

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: August 25, 2025
Received: August 25, 2025

Dear Jessica Meyer:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252681

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Please provide the device trade name(s).

?

EnCor EnCompass™ Breast Biopsy and Tissue Removal System

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?



EnCor EnCompass™ Breast Biopsy and Tissue Removal System

510(k) Summary - K252681

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) 830-5070
Fax: (312) 949-0436

Contact Person: Jessica Meyer, Regulatory Affairs Specialist
Date of Submission: August 25, 2025

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 Enspire™ Breast Biopsy System (K233220, cleared on October 27, 2023)

Reference Device:

Brevera® Breast Biopsy System with Corlumina Imaging Technology (K163052)

ATEC® Breast Biopsy System (K042290)

Marquee™ Disposable Core Biopsy Instrument and Instrument Kit (K250032)

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 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 devices, the EnCor Enspire™ Breast Biopsy System, Drivers, and Probes (K233220, cleared on October 27, 2023).

- Same intended use
- Same indications for use
- Same target patient population
- Same principle of operation
- Same fundamental scientific technology
- Same imaging compatibilities
- Same sterility level and method of sterilization
- Same general packaging configuration

All components of the subject device are of similar design and function as the components of the predicate device. The changes between the subject device and the predicate device(s) include:

- Enhanced user interface
- Enhanced sampling options
- Reduced inventory requirements
- Addition of wireless technology
- Patient contacting materials

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 non-clinical testing of medical devices, recognized consensus standards, and internal risk assessment procedures:

- ISO 10993 Series
- IEC 60601 Series
- IEC 62366-1
- IEC 62304
- ASTM F2096
- ASTM F2503

- AAMI TIR12
- ANSI AAMI ST98
- “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (September 2023)
- “Applying Human Factors and Usability Engineering to Medical Devices” (February 3, 2016)
- “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” (March 17, 2015)
- “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” (October 10, 2023)
- “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (September 27, 2023)
- “Electromagnetic Compatibility of Medical Devices” (June 6, 2022)

The following tests were performed:

- Performance Testing
 - Reliability
 - Mechanical/Tensile Testing
 - Tissue Penetration
 - Sample Mass and Contiguity
 - Needle Throw Length
 - Stereotactic Imaging Mount Test
 - Lavage
- Design Validation
- Packaging Validation
- Sterilization Validation
- Biocompatibility
- Human Factors Evaluation
- Electrical Safety and EMC
- Reprocessing Validation
- Software Testing
- Cybersecurity Testing
- Wireless Testing
- MR 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 EnCor EnCompass™ Breast Biopsy and Tissue Removal System, and the predicate device share the same or similar characteristics: intended use, indications for use, target patient population, principle of operation, fundamental scientific technology, imaging compatibility, sterility level and method of sterilization, and general packaging configuration. Additionally, the EnCor EnCompass™ Breast Biopsy and Tissue Removal System met predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Therefore, BD concludes that the subject device, the EnCor EnCompass™ Breast Biopsy and Tissue Removal System, is substantially equivalent to the legally marketed predicate device, the EnCor Enspire™ Breast Biopsy System.