March 30, 2022

Bard Peripheral Vascular, Inc.
Mrs. Kristen DeJeu, BSN, RN
Sr. Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K213896
Trade/Device Name: BD Trek™ Bone Marrow Biopsy System
BD Trek™ Bone Lesion Biopsy System

Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 24, 2022
Received: February 28, 2022

Dear Ms. DeJeu:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213896

Device Name
BD Trek™ Bone Marrow Biopsy System
BD Trek™ Bone Lesion Biopsy System

Indications for Use *(Describe)*
The BD Trek™ Bone Marrow Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Marrow Biopsy Kit) is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.

The BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Lesion Biopsy Kit) is intended for bone biopsy of the vertebral body and bone lesions.
The BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Lesion Biopsy Kit) is intended for bone marrow aspiration and biopsy.

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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K213896

Becton, Dickinson and Company
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281

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 as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, AZ 85281
Phone: Fax:	(602) 894-9515 (312) 949-0436
Manufacturer/510(k) Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, AZ 85281 Contact: Mrs. Kristen DeJeu, BSN, RN Title: Sr. Regulatory Affairs Specialist Email: Kristen.DeJeu@bd.com Phone: (602) 830-5333
Date:	25 March 2022

2. Subject Device Name:

Device Trade Name:	BD Trek™ Bone Marrow Biopsy System BD Trek™ Bone Lesion Biopsy System
Common or Usual Name:	Bone Marrow Biopsy Needle Bone Biopsy and Biopsy Needle
Classification:	Class II KNW (Gastroenterology-urology biopsy instrument)
Review Panel:	Gastroenterology / Urology
Regulation Number:	21 CFR 876.1075

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Tempe, AZ 85281

3. Predicate Device:

Device Trade Name:	OnControl™ Bone Marrow Biopsy System by Vidacare™ OnControl™ Bone Access and Bone Biopsy System by Vidacare™
510(k) Number:	K142377, K113872
Common or Usual Name:	Bone Marrow Biopsy Needle, Cement Dispenser Conduit for Vertebroplasty and Bone Biopsy Needle
Classification:	Class II KNW (Gastroenterology-urology biopsy instrument)
Regulation Number:	21 CFR 876.1075

4. Subject Indications for Use:

The BD Trek™ Bone Marrow Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Marrow Biopsy Kit) is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.

The BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Lesion Biopsy Kit) is intended for bone biopsy of the vertebral body and bone lesions.
The BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Lesion Biopsy Kit) is intended for bone marrow aspiration and biopsy.

5. Subject Device Description:

The BD Trek™ Bone Marrow Biopsy System and Bone Lesion Biopsy System consists of a variable speed Power Driver and compatible BD Trek™ Biopsy Kits.

The BD Trek™ Power Driver is a handheld, battery-powered, reusable bone drill. The Power Driver has a variable speed function which is controlled by the amount of pressure applied to the trigger. Applying light pressure on the trigger activates the drill at a low speed and increasing trigger pressure activates higher speeds. Full depression of the trigger will activate the maximum speed. Full release of the trigger will stop the motor function.
The BD Trek™ Bone Biopsy Kits are single-use bone biopsy kits designed exclusively for use with the BD Trek™ Power Driver. The BD Trek™ Power Driver is reusable and is supplied non-sterile. The BD Trek™ Bone Biopsy Kits are supplied sterile, non-pyrogenic, and are available in different needle gauge sizes and lengths.

6. Technological Comparison to Predicate Device:

The table below provides a technological comparison between the subject devices and the predicate devices. The information following the table provides a discussion between the similarities and differences of these devices.

Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **BD Trek™ Powered Bone Biopsy System** BD Trek™ Bone Marrow Biopsy System BD Trek™ Bone Lesion Biopsy System
Regulation Number		21 CFR 876.1075	21 CFR 876.1075
Class		II	II
Primary FDA Product Code		KNW - Instrument, Biopsy	KNW – Instrument, Biopsy
Indications for Use	Bone Marrow	The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.	The BD Trek™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.
	Bone Lesion	The OnControl™ Bone Access and Bone Biopsy System is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and/or for bone biopsy of the vertebral body and bone lesions.	The BD Trek™ Bone Lesion Biopsy System is intended for bone biopsy of the vertebral body and bone lesions. The BD Trek™ Bone Lesion Biopsy System is intended for bone marrow aspiration and biopsy.
Target Population	Bone Marrow	Adult and pediatric patients needing bone marrow aspiration or bone marrow biopsy.	Adult and pediatric patients needing bone marrow aspiration or bone marrow biopsy.
	Bone Lesion	Patients requiring fixation of fractures of the vertebral body or bone biopsy.	Patients requiring bone biopsy. Patients needing bone marrow aspiration or bone marrow biopsy.
Fundamental Scientific Technology		Power Driver with Needle Attachments	Power Driver with Needle Attachments
Power Driver Design		Cordless, lithium battery-powered; reusable with disposable sterile sleeve	Cordless, lithium battery-powered; reusable with disposable sterile sleeve
Power Driver Energy Delivered		Non-Accessible, Internal, 18 V Lithium Battery	Non-Accessible, Internal, 18 V Lithium Battery
Power Driver Cybersecurity/Interfaces		Does not contain any external wired and/or wired communication interfaces	Does not contain any external wired and/or wired communication interfaces

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Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **BD Trek™ Powered Bone Biopsy System** BD Trek™ Bone Marrow Biopsy System BD Trek™ Bone Lesion Biopsy System
Needle Design		Sterile, single-use, disposable	Sterile, single-use, disposable
Operating Principle		Needle set attaches to battery-powered driver	Needle set attaches to battery-powered driver
Mode of Action		Single puncture, bone access, and sample	Single puncture, bone access, and sample
Energy Used / Delivered		Lithium battery provides rotational kinetic energy to aid the physician in inserting and advancing the needle through cortical and/or cancellous bone	Lithium battery provides rotational kinetic energy to aid the physician in inserting and advancing the needle through cortical and/or cancellous bone
Imaging Compatibility		X-Ray / CT and Ultrasound Compatibility	X-Ray / CT and Ultrasound Compatibility
Speed		Single-Speed	Variable
Power Driver Motor Braking		No Braking Feature	Braking Feature upon Trigger Release
Kit Components	Bone Marrow	OnControl™ Bone Marrow Biopsy Tray 1. Alignment Guide 2. Biopsy Needle 3. Depth Stop 4. Ejector Rod 5. Connector Hub with Sterile Sleeve 6. Fenestrated Drape	BD Trek™ Bone Marrow Biopsy Kit 1. Ejector Guide 2. Biopsy Cannula and Stylet (Needle Assembly) 3. Needle Grip 4. Ejector Rod 5. Manual Driver 6. Sterile Sleeve with Quick Connect Hub 7. Fenestrated Drape
	Bone Lesion	OnControl™ Bone Lesion Biopsy Tray 1. Transfer Rod 2. Bone Access Ejector Rod 3. Bone Access Needle Set 4. Bone Lesion Biopsy Needle 5. Bone Lesion Biopsy Ejector Rod 6. Depth Stop 7. Manual Handle 8. Connector Hub with Sterile Sleeve 9. Fenestrated Drape 10. Ejector Assist	BD Trek™ Bone Lesion Biopsy Kit 1. Transfer Rod 2. Introducer Ejector Rod 3. Introducer Cannula and Stylet 4. Biopsy Cannula 5. Biopsy Ejector Rod 6. Needle Grip 7. Manual Driver 8. Sterile Sleeve with Quick Connect Hub 9. Fenestrated Drape
Gauge Sizes	Bone Marrow	Biopsy Cannula: 11G	Biopsy Cannula: 11G

Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **BD Trek™ Powered Bone Biopsy System** BD Trek™ Bone Marrow Biopsy System BD Trek™ Bone Lesion Biopsy System
	Bone Lesion	Access Cannula: 10G and 11G Biopsy Cannula: 12G and 13G	Introducer Cannula: 10G and 11G Biopsy Cannula: 12G and 13G
Overall Needle Assembly Length	Bone Marrow	Biopsy Needle Assembly: 102 and 152 mm	Biopsy Needle Assembly: 100 and 150 mm
	Bone Lesion	Bone Access Needle Assembly: 62, 102 and 152 mm	Introducer Needle Assembly: 60, 100 and 150 mm
		Biopsy Needle Assembly: 108, 148, and 198 mm	Biopsy Needle Assembly: 108, 148, 198 mm
Biopsy Kits - Sterility		Single Use, Ethylene Oxide	Single Use, Ethylene Oxide
Power Driver - Sterility		Reusable, non-sterile. Used with Single Use Disposable Sterile Sleeve with Connector Hub	Reusable, non-sterile. Used with Single Use Disposable Sterile Sleeve with Quick Connect Hub
Power Driver - Disinfection		Disinfected utilizing an antimicrobial solution	Disinfected utilizing an antimicrobial solution

The predicate device is the OnControl™ Powered Bone Biopsy System, which is comprised of the *OnControl™ Bone Marrow Biopsy System* and the *OnControl™ Bone Access and Bone Biopsy System*. The OnControl™ Bone Biopsy System is referenced as the predicate device for the BD Trek™ Bone Biopsy System as it is the same or similar to the subject device in the following ways:

1. Intended Use
2. Indications for Use
    a. The BD Trek™ Bone Marrow Biopsy System shares the same indications for use as the predicate's Bone Marrow Biopsy System.
    b. The BD Trek™ Bone Lesion Biopsy System shares the same indications for use as the predicate, OnControl™ Bone Marrow Biopsy System, and also utilizes a subset of the indications from the predicate, the OnControl™ Bone Access and Bone Biopsy System. Indications for vertebroplasty have been omitted.
3. Performance Characteristics
4. Target Population
5. Fundamental Scientific Technology
6. Operating Principle, Mechanism of Action
7. Sterility Assurance Level and Method of Sterilization

The subject device is different from the predicate device in the following ways:

1. Combined Marrow/Lesion Indications for the BD Trek™ Bone Lesion Biopsy System
2. Enhanced Power Driver Technology
    a. Variable Speed Functionality: The subject device utilizes a variable speed Power Driver. The variable speed functionality was designed to allow the user to control the speed of the needle rotation depending on their needs and the type of procedure being performed.
    b. Motor Brake Function: The subject device's brake control stops the needle rotation upon trigger release through dynamic braking.
    c. Reference LED Indicator that displays Relative Speed: The subject device utilizes a Reference LED indicator that displays motor state, battery life, and relative speed.
3. Biopsy Kit Components
    a. Optimized Biopsy and Introducer Cannula Dimensions and Tip Design: The subject device Biopsy and Introducer Cannulas feature enhanced designs for optimal sample acquisitions.
    b. T-Handle Manual Driver: The subject device's Manual Driver is a T-Handle and attaches to the needle assembly via interfacing and a locking mechanism.
    c. Quick Connect Release Mechanism: The subject device was designed to release the Needle Assembly from the Power Driver by retracting the Quick Connect Hub (in the same manner as the predicate device) or advancing the Release Arm forward.

7. Performance Data:

To demonstrate that the BD Trek™ Powered Bone Biopsy System is as safe and effective as the predicate, the technological characteristics and performance criteria were evaluated. Using internal risk assessment procedures, tests of the following characteristics and performance criteria were performed on the subject device:

- Membrane Penetration Force
- Tissue Sampling
- Reliability Testing – Sterile Sleeve
- Tensile Strength – Needle Hub
- Dead Space Measurements
- Luer Testing
- Creep Testing
- Power Driver Battery Life
- Power Driver Drive Adapter Reliability

Additionally, biocompatibility testing was performed in accordance with ISO 10993-1 to demonstrate that the BD Trek™ Powered Bone Biopsy System is biocompatible for its intended use. Sterilization was performed in accordance with 11135:2014 to confirm the Sterility Assurance Level (SAL) of 10^{-6} for the BD Trek™ Biopsy Kits. Electromagnetic Compatibility and Electrical Safety Testing was performed on the BD Trek™ Power Driver in accordance with IEC 60601-1 and 60601-1-2. The results from this testing demonstrate the BD Trek™ Power Driver meets electrical safety and performance requirements established, and acceptance criteria for all tests were met.

The subject device, BD Trek™ Bone Marrow Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Marrow Biopsy Kit) and BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Lesion Biopsy Kit), met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs.

8. Conclusion:

The subject device and the predicate device share the same or similar characteristics: intended use, indications for use, target population, conditions for use, and fundamental scientific technology. As such, Bard Peripheral Vascular, Inc. has demonstrated that the subject device BD Trek™ Bone Marrow Biopsy System (BD Trek™ Power Driver, BD Trek™ Bone Marrow Biopsy Kit) and BD Trek™ Bone Lesion Biopsy System (BD Trek™ Power Driver, BD Trek Bone Lesion Biopsy Kit) is substantially equivalent to the legally marketed predicate device OnControl™ Bone Marrow Biopsy System and OnControl™ Bone Access and Bone Biopsy System, respectively.