September 14, 2017

Bard Peripheral Vascular, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN  55313

Re:   K171953
Trade/Device Name:  Bard® Mission® Disposable Core Biopsy Instrument
Regulation Number:  21 CFR§ 876.1075
Regulation Name:  Gastroenterology-Urology Biopsy Instrument
Regulatory Class:  II
Product Code:  KNW
Dated:  September 5, 2017
Received:  September 6, 2017

Dear Mark Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Bard® Mission® Disposable Core Biopsy Instrument is intended for use in obtaining biopsy samples from soft tissues such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.

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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BARD® MISSION® Disposable Core Biopsy Instrument
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: 480-350-6067
Fax: 480-449-2570
Contact: Susan Sheffield, Regulatory Affairs Associate
Date 15 May 2017

Subject Device Name:

Device Trade Name: Bard® MISSION® Disposable Core Biopsy Instrument
Common or Usual Name: Core Biopsy Instrument
Classification: Instrument, Biopsy (Product Code KNW); Class II

Review Panel: Gastroenterology / Urology
Regulation Number: 21 CFR 876.1075

Predicate Devices:
- M-Biopsy™ Semi-Automatic Biopsy Instrument by Mermaid Medical (K161409; cleared 2 August 2016)
- BARD® MONOPTY® and BARD® MAX-CORE® Disposable Core Biopsy Instruments (K133948/S001; cleared 21 February 2014)

Reference Devices:
- POWERGLIDE® Midline Catheter (K121073; cleared 1 June 2012)
- ULTRACLIP® DUAL TRIGGER Breast Tissue Marker (K042341; 20 September 2004)
- ENCOR® Breast Biopsy System (K051158; 16 May 2005)
- SIDEKICK® and USHER® Support Catheters (K131493; cleared 2 August 2013)

The purpose of the secondary predicate device BARD® MAX-CORE®/MONOPTY® is to highlight similarities to the branding for BARD® disposable core biopsy devices. The reference
devices are included to provide sufficient evidence for the safe usage of the materials found in BARD® MISSION®.

**Device Description:**

The subject device BARD® MISSION® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The plunger is color coded according to the various gauge sizes, e.g. yellow = 20 gauge, pink = 18 gauge, purple = 16 gauge, and green = 14 gauge.

**Indications for Use of Device:**

The BARD® MISSION® Disposable Core Biopsy Instrument is intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.

**Technological Comparison to Predicate Device:**

The subject device BARD® MISSION® has the following similarities to the primary predicate device M-Biopsy™:

- Same class and regulation number
- Same Intended Use
- Similar Indications for Use
- Same Target Population/Conditions of Use (anatomical location of use, user interface, how device interacts with other devices, interaction with patient, etc.)
- Same Fundamental Scientific Technology, including Design, Mechanism/Mode of Action, and Energy Used/Delivered
- Same catalogue offerings, including Gauge Size, Needle Length, and Penetration Depth
- Similar design features, such as Centimeter Markings, Grip Design, Color Coding, and Echogenicity
- Same imaging capabilities

The subject device BARD® MISSION® Disposable Core Biopsy Instrument incorporates the following differences:

- Slight alterations to the language used in the Indications for Use in order to maintain consistency in branding for the BARD® Disposable Core Biopsy products
- Different dimensions of the Specimen Notch used to collect the biopsy sample
- Differences in design, such as the Finger Grips and Fire Ready Indicator
- Unknown differences, such as:
  - Color Coding
  - Echogenic Enhancement
  - Sterility Assurance
Performance Data:

To demonstrate that the subject device BARD® MISSION® is as safe and as effective as the predicate device M-Biopsy™, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following in vitro tests were performed on the subject device:

- Number of Samples
- Penetration Depths
- Stylet / Cannula to Handle Tensile Strength
- Corresponding Working Needle Length and Cutting Cannula OD, and Stylet/Cannula Working Needle Lengths
- Integrity of the Sterile Barrier
- Performance After Ship Testing
- Needle Protection After Shipping and Storage

The results from bench testing demonstrate that the subject device BARD® MISSION® performed as expected according to the technological characteristics and performance requirements of C.R. Bard; and thus, can be concluded as comparable to other semi-automatic core biopsy devices on the market, demonstrating the subject device BARD® MISSION® to be as safe, as effective, and performs as well as the legally marketed device M-Biopsy™.

Biocompatibility:

Per ISO 10993-1:2009, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.” The following biocompatibility tests were successfully performed and/or adopted in accordance with GLP regulations:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Material Mediated Pyrogenicity

The results of biocompatibility testing demonstrate that the subject device BARD® MISSION® is considered biocompatible for its intended use.

Conclusions:

The subject device, BARD® MISSION® Disposable Core Biopsy Instrument, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Likewise, the subject device BARD® MISSION® and the predicate device M-Biopsy™ share the same or similar characteristics: intended use, indications for use, target population / conditions for use, and fundamental scientific technology. Therefore, Bard concludes that the subject device BARD® MISSION® Disposable Core Biopsy Instrument is substantially equivalent to the legally marketed predicate device M-Biopsy™ Semi-Automatic Biopsy Instrument.