March 9, 2018

Bard Peripheral Vascular, Inc.
Meghan McKelvey
Regulatory Affairs Associate
1625 W. 3rd Street
Tempe, Arizona 85281

Re: K180061
Trade/Device Name: UltraCor Twirl Breast Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: January 5, 2018
Received: January 8, 2018

Dear Ms. McKelvey:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180061

Device Name
UltraCor® Twirl® Breast Tissue Marker

Indications for Use *(Describe)*
The UltraCor® Twirl® Breast Tissue Marker is intended for use to attach to soft breast tissue, including axillary lymph nodes, to radiographically mark the location of the biopsy procedure.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ULTRACOR® Twirl® Breast Tissue Marker
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:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: (480) 350-6153

Fax: (480) 966-7062

Contact: Meghan McKelvey, Regulatory Affairs Associate

Date January 5, 2018

2. Subject Device Names:

Device Trade Name:	**ULTRACOR® TWIRL® Breast Tissue Marker**
Common or Usual Name:	Breast Tissue Marker
Classification:	Class II
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4300 (FDA Product Code NEU)

3. Predicate Devices:

Predicate 510(k) Number	Subject Device
K152510; cleared May 13, 2016	**ULTRACOR® TWIRL®**

4. Summary of Change

The Indications for Use statement is being updated to include the axillary lymph nodes. Subject device labeling updates including updates to the Instructions for Use and Potential Complications, are being implemented through this submission.

5. Device Description:

The ULTRACOR® Twirl® Breast Tissue Marker consists of a disposable beveled needle applicator containing a nitinol radiographic ring wireform. The wireform is intended for long-term radiographic marking of the tissue site. The applicator has a beveled 17G x 10cm needle with 1cm depth marks and a locking plunger. The ring is deployed from the beveled needle tip into the tissue site.

6. Indications for Use of Device:

The ULTRACOR® Twirl® Breast Tissue Marker is intended for use to attach to soft breast tissue, including axillary lymph nodes, to radiographically mark the location of the biopsy procedure.

7. Technological Comparison to Predicate Devices:

The ULTRACOR® Twirl® Breast Tissue Marker has the following similarities to the predicate device:

- Same Intended Use
- Same Target Population
- Same Technological Characteristics
- Same Fundamental Scientific Technology
- Same Operating Principal
- Same Implant Design and Materials
- Same Applicator Design and Materials
- Same Performance Specifications
- Same Packaging Materials and Configurations
- Same Sterility Assurance Level and Method of Sterilization

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

- Modifications to Indications for Use

There are no changes to the implants or delivery systems. The subject device labeling has been updated to include the updated Indications for Use language.

8. Performance Data:

The change to the Indications for Use described in this submission does not affect the design of the device and no new or increased risks have been identified, therefore additional bench performance testing was not warranted.

9. Clinical Analysis:

The change to the Indications for Use is clinically supported by both a comprehensive literature review and physician statements. A comprehensive literature review was conducted to collect and assess relevant clinical literature related to the use of clips (breast tissue markers) in axillary lymph nodes in metastatic breast cancer patients. To further reinforce the clinical use of a breast tissue marker in the axillary lymph node region, Bard consulted with physicians to gain further insight on current practices.

10. Conclusions:

The subject device, ULTRACOR® Twirl® Breast Tissue Marker, is substantially equivalent to the legally marketed predicate device.