DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 13, 2016

Bard Peripheral Vascular, Inc.
Ms. Kristen Dejeu
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, Arizona 85281

Re: K152510
Trade/Device Name: Ultracore Twirl Breast Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 12, 2016
Received: April 13, 2016

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. 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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152510

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 at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy 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.

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510(k) Summary
[As required by 21 CFR 807.92(c)]

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 summary of the information 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:	480-449-2546
Contact:	Kristen DeJeu, Regulatory Affairs Associate
Date:	May 11, 2016

Subject Device:

Device Trade Name:	**UltraCor® Twirl™ Breast Tissue Marker**
Common or Usual Name:	Breast Tissue Marker
Classification:	Class 2
Classification Name:	Marker, Radiographic, Implantable (Product Code NEU)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4300 (Implantable Clip)

Predicate Device:

UltraClip® II US Wing and Coil (K090547, Cleared March 18, 2009)

Summary of Change:

The modifications from the predicate device, the UltraClip® II US Wing and Coil Breast Tissue Marker, to the subject device, the UltraCor® Twirl™ Breast Tissue Marker, include differences in marker design and material, applicator design and material, packaging material, and labeling.

Device Description:

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

Indications for Use of Device:

The UltraCor® Twirl™ Breast Tissue Marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

Technological Characteristics:

The UltraCor® Twirl™ has the following similarities to the predicate device:

- Same intended use / indications for use
- Similar technological characteristics
- Same fundamental scientific technology
- Same target population
- Same operating principle
- Same sterility assurance level
- Same method of sterilization
- Same packaging configuration

Performance Testing Summary:

Bench testing was performed to verify that the modifications to the subject device do not impact safety or effectiveness of the device. Design verification and validation testing included: marker shape distinguishability, ultrasound visibility, marker deployment accuracy, marker deployment force, marker deployment, marker retention, marker dimensional testing, applicator dimensional testing, applicator tensile testing, visual inspection of the product, visual integrity of the packaging, pouch seal strength of the packaging, MRI testing (magnetic field interactions, MRI-related heating, artifact testing), as well as biocompatibility testing on the applicator and the marker implant.

Conclusion:

The subject device, the UltraCor® Twirl™ Breast Tissue Marker, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Therefore, the UltraCor® Twirl™ Breast Tissue Marker is substantially equivalent to the legally marketed predicate device, the UltraClip II US Wing and Coil Breast Tissue Marker (K090547).