March 24, 2025

Bard Peripheral Vascular, Inc.
Meghan Mckelvey
Regulatory Affairs Manager
1625 West 3rd Street
Tempe, Arizona 85281

Re: K243642
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: November 25, 2024
Received: November 26, 2024

Dear Meghan 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 (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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K243642

Device Name
The UltraCor™ Twirl™ Breast Tissue Marker (Curls and Clover)

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.

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510(k) Summary

21 CFR 878.4300

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:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	602-830-5063
Contact:	Meghan McKelvey, Regulatory Affairs Manager
Date:	November 26, 2024

2. Subject Device-K243642:

Device Trade Name:	**UltraCor™ Twirl™ Breast Tissue Marker (Curls and Clover)**
Classification Name:	Marker, Radiographic, Implantable (Product Code: NEU)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4300

3. Predicate Device:

UltraCor™ Twirl™ Breast Tissue Marker (Ring shape; K180061)

4. Device Description:

The UltraCor™ Twirl™ Breast Tissue Marker (Curls and Clover) consists of a disposable beveled needle applicator containing a Nitinol radiographic 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. Each marker shape is deployed from the beveled needle tip into the tissue site.

5. 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.

6. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended Use
- Indications for Use
- Performance Characteristics
- Target Population
- Fundamental Scientific Technology
- Operating Principle (Mechanism of Action)
- Wireform (Marker) Material
- Sterility Assurance Level and Method of Sterilization
- Shelf-Life
- Packaging Configuration

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

- Marker Shapes
- Applicator Handle Overmold Colorants

7. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA Guidance document, “Design Control Guidance for Medical Device Manufacturers,” dated March 11, 1997, and internal risk assessments procedures, the following non-clinical tests were performed:

- Marker Differentiation (Stereotactic or X-Ray/Mammography)
- Marker Visibility (Ultrasound, Stereotactic, X-Ray/Mammography, MRI)
- Marker Retention Testing
- Marker Deployment Accuracy
- Marker Deployment Force
- Marker Deployment
- Corrosion Testing of Wireform (Marker)

- Nickel Ion Release Testing
- Transformation Temperature Testing
- MRI Testing, and
- Biocompatibility Testing was conducted on both the wireform (marker) and the applicator as presented in Table 1.

Table 1: Biocompatibility Testing of UltraCor Twirl Breast Tissue Marker (Curls and Clover shapes)

Implantable Wireform (Marker)	
Test Method	**Results**
Chemical characterization Exhaustive Extraction at 50°C for 72 hours (in triplicate)	Pass SVOC by GC/MS VOC by GC/MS by Headspace ICP/MS NVOC by UPLC/MS
Cytotoxicity	
MEM Cell Cytotoxicity	Pass
Sensitization (Kligman Maximization)	Pass
Irritation / Intracutaneous Reactivity (Intracutaneous Injection)	Pass
Acute Systemic Toxicity	Pass
Material Mediated Pyrogenicity	Pass
Subchronic Toxicity Study in Rats (13 weeks)	Pass
Genotoxicity • AMES Assay • Mouse Lymphoma Assay	• Pass • Pass
Implantation • 1 week • 4 weeks • 12 weeks	• Pass • Pass • Pass
Toxicology (Toxicological Risk Assessment)	Pass
Applicator	
Aqueous Physicochemical Testing	Pass Extract – Purifed Water
Non-Aqueous Physicochemical Testing	Pass Extract – Isopropyl Alcohol
Exaggerated Extraction	Pass Extract – Purified Water Extract – Isopropyl Alcohol Extract – Cyclohexane
Cytotoxicity	Pass

	Extract – MEM Elution
Sensitization–Kligman Guinea Pig Maximization	Pass Extract – 0.9% Sodium Chloride Extract – Cottonseed oil
Irritation or Intracutaneous Reactivity	Pass Extract – 0.9% Sodium Chloride Extract – Cottonseed oil
Acute Systemic Toxicity	Pass Extract – 0.9% Sodium Chloride Extract – Sesame oil
Material-Mediated Pyrogenicity	Pass Extract – 0.9% Sodium Chloride
Chemical Characterization	Pass SVOC by GC/MS VOC by GC/MS by Headspace ICP/MS NVOC by UPLC/MS

The biologic and chemical characterization test results demonstrate that the subject device is biocompatible for its intended use. The technological characteristics and performance criteria of the UltraCor™ Twirl™ Breast Tissue Marker (Curls and Clover) are comparable to the predicate device and that they perform as safely and as effectively as the legally marketed predicate device.

8. Conclusion:

The UltraCor™ Twirl™ Breast Tissue Marker (Curls and Clover) are substantially equivalent to the legally marketed predicate device, the UltraCor™ Twirl™ Breast Tissue Marker (Ring shape; K180061).