December 12, 2025

Breast-Med Inc
℅ Yidi Hou
Program Manager
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K251989
Trade/Device Name: VizMark Preloaded Tissue Marker Device (VM-0001)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: November 20, 2025
Received: November 20, 2025

Dear Yidi Hou:

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 Plastic and
Reconstructive Surgery Devices
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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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251989

Device Name
VizMark Preloaded Tissue Marker Device (VM-0001)

Indications for Use *(Describe)*
The VizMark Preloaded Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

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 (K251989)

## Submitter's Name, Address and Date of Submission

Breast-Med Inc.

Michael Nelson, M.D.
Breast-Med Inc.
10580 Wayzata Blvd. Suite 150
Hopkins, MN 55305-1561

Phone: 952-600-2934

Date Prepared: August 01, 2025

## Device Name

| | |
|---|---|
| Trade Name: | VizMark Preloaded Tissue Marker Device |
| Classification Name: | Marker, Radiographic, Implantable |
| Regulation Number: | 21 CFR 878.4300 |
| Regulatory Class: | II |
| Product Code: | NEU |
| Common/Usual Name: | Marker, Radiographic, Implantable |

## Predicate Name

| | |
|---|---|
| Trade Name: | Breast-Med Tissue Marker (K133697) |
| Classification Name: | Marker, Radiographic, Implantable |
| Regulation Number: | 21 CFR 878.4300 |
| Regulatory Class: | II |
| Product Code: | NEU |
| Common/Usual Name: | Marker, Radiographic, Implantable |

## Device Description

The VizMark Tissue Marker is a sterile, nonpyrogenic, single use tissue marker consisting of a gadolinium filled polymeric tube that is visible on standard radiographs (x-ray, mammography) as well as ultrasound and Magnetic Resonance Imaging (MRI). The tissue marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. VizMark Preloaded Tissue Markers are supplied pre-loaded in a sterile, single patient use delivery device.

## Indication for Use

The VizMark Preloaded Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

**Technological Characteristics**

The subject device, VizMark Pre-Loaded Tissue Marker Device, is substantially equivalent to the predicate device (K133697) with respect to fundamental technology, intended use, and indications for use. Both devices are sterile, single-use tissue markers intended for long-term implantation at biopsy sites. The VizMark Pre-Loaded Tissue Marker Device uses the same tissue marker as the predicate device and delivery mechanism as the reference device. While the VizMark system incorporates a different sterile barrier pouch, retention mechanism, and delivery needle, these changes do not alter the device's core technological characteristics. The marker itself remains unchanged and functionally equivalent. Performance testing and risk-based justification confirm that these packaging and component updates do not raise new questions of safety or effectiveness. Therefore, no new clinical data is required to support this determination of substantial equivalence.

## Substantial Equivalent Comparison with the Predicate Device

The VizMark Preloaded Tissue Marker Device [subject device] is substantially equivalent (SE) to the Breast-Med Tissue Marker [predicate device] (K133697) and Preloaded Tissue Marker Device [reference device] (K100994) based on the similar functional and performance characteristics of the subject device when compared to the predicate/reference devices. The minor differences between the subject device and predicate device regarding the delivery system, sterile barrier, and shelf life do not raise concerns of safety and effectiveness.

A side-by-side comparison of the technological characteristics of the subject device and the predicate/reference devices, supports a determination of substantial equivalency (SE) per the table below.

| Characteristic | Proposed Device | Predicate Device | Reference Device | Comparison |
|---|---|---|---|---|
| **Trade Name** | VizMark Preloaded Tissue Marker Device | Breast-Med Tissue Marker | Preloaded Tissue Marker Device | |
| **510(k) Number** | K251989 | K133697 | K100994 | |
| **510(k) Holder** | Breast-Med | Breast-Med | Carbon Medical Technologies | |
| **Indication For Use** | To radiographically mark soft tissue during a surgical procedure or for future surgical procedures. | To radiographically mark soft tissue during a surgical procedure or for future surgical procedures. | To radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures. | **Same** |
| **Use** | Single Use | Single Use | Single Use | **Same** |
| **Marker Visualization Modalities** | Visible on standard radiographs (X-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI). | Visible on standard radiographs (X-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI). | Visible on standard radiographs (X-ray, CT, mammography, fluoroscopy, kV) as well as ultrasound, and Magnetic Resonance Imaging (MRI). | **Same** |

| Characteristic | Proposed Device | Predicate Device | Reference Device | Comparison |
|---|---|---|---|---|
| **Radiopaque Marker Material** | PEEK, BaSO4 filled PEEK and Gd/chelate | PEEK, BaSO4 filled PEEK and Gd/chelate | Pyrolytic Carbon Coated Zirconium Oxide marker incorporated into lyophilized glucan gel | **Same as predicate device** |
| **Delivery System** | 14GA delivery device manufactured by Carbon Medical Technologies | Insert through a commercially available device using a minimum diameter equivalent to the 13GA needle | 8-14GA delivery device manufactured by Carbon Medical Technologies | **Same as reference device** |
| **Cannula Type** | Rigid | N/A | Rigid | **Same** |
| **Cannula Material** | Stainless Steel | N/A | Stainless Steel | **Same** |
| **Plunger Rod Material** | Stainless Steel | N/A | Stainless Steel | **Same** |
| **Handle** | Plastic Polymer | N/A | Plastic Polymer | **Same** |
| **Retention Mechanism** | Detent | N/A | Nylon Sleeve | **Substantially Equivalent** |
| **Marker contact category** | Implant device, tissue, permanent | Implant device, tissue, permanent | Implant device, tissue, permanent | **Same** |
| **Sterile barrier packaging** | BOPA/Polyethylene/Foil with chevron feature | Uncoated Tyvek with polyethylene laminate pouch | BOPET/Polyethylene/Foil with chevron feature | **Substantially Equivalent** |
| **Sterility Assurance Level (SAL)** | $> 1\times10^{-6}$ | $> 1\times10^{-6}$ | $> 1\times10^{-6}$ | **Same** |
| **Sterilization Method** | Gamma Irradiation | Gamma Irradiation | Gamma Irradiation | **Same** |
| **Shelf Life** | 24 months | 12 months | 6 months | **Substantially Equivalent** |
| **MR Status – Marker** | MR Safe | MR Safe | MR Conditional | **Same as predicate device** |
| **MR Status – Applicator** | MR Unsafe | N/A | MR Unsafe | **Same** |

**Tests performed to evaluate and compare technological and performance characteristics:**

Non-Clinical bench performance testing was conducted on the VizMark Preloaded Tissue Marker Device [subject device] to confirm that the device meets all system requirements and is substantially equivalent to Breast-Med Tissue Marker (K133697) [predicate device]. The following Verification Data was provided in support of the substantially equivalence determination.

- Performance Testing – Bench
  - Marker Delivery
  - Marker Integrity
  - Handle Pull Test
- Sterilization
- Packaging
- Shelf Life
- Biocompatibility:
  - Biocompatibility testing was conducted on the delivery system, which represents the components newly introduced in the subject device. The following biological endpoints were evaluated, and all test results met acceptance criteria:

    - Cytotoxicity (ISO 10993-5): Non-cytotoxic
    - Sensitization (ISO 10993-10): Non-sensitizing
    - Irritation / Intracutaneous Reactivity (ISO 10993-10): Non-irritating
    - Acute Systemic Toxicity (ISO 10993-11): Non-toxic
    - Pyrogenicity (ISO 10993-11): Non-pyrogenic

    The implantable tissue marker component is identical in material composition, manufacturing process, and intended use to the marker used in the Breast-Med Tissue Marker [predicate device]. Therefore, previously reviewed biocompatibility data for the predicate device were leveraged to support the biological safety of the marker component.

    Based on the testing performed and the use of predicate data, the VizMark Preloaded Tissue Marker Device [subject device] is considered biocompatible and suitable for its intended use.

**Conclusions:**

The data generated from the results of the Verification Testing, Design Validation, along with a side-by-side comparison of the technological characteristics of design, components, and materials of construction between the subject device and the predicate and reference device, demonstrate that the VizMark Preloaded Tissue Marker Device [subject device] is as safe and effective and performs as well as the Breast-Med Tissue Marker [predicate device].

The similar technological and performance characteristics for the proposed VizMark Preloaded Tissue Marker Device [subject device] have been assessed to be substantially equivalent to the predicate device, and any differences in delivery system, sterile barrier packaging, and shelf life do not raise concerns of safety and effectiveness when compared to the predicate or reference device. Therefore, the VizMark Preloaded Tissue Marker Device [subject device] is substantially equivalent to the predicate device.