July 23, 2025

Carbon Medical Technologies, Inc.
Yidi Hou
Program Manager - Regulatory and Clinical
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K251748
Trade/Device Name: MammoSTAR Biopsy Site Identifier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 20, 2025
Received: June 6, 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
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)*
K251748

Device Name
MammoSTAR Biopsy Site Identifier

Indications for Use *(Describe)*
MammoSTAR Biopsy Site Identifier is indicated for use to radiographically mark soft tissue at the surgical site 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.

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."

510(K) SUMMARY

K251748

Submitter's Name, Address and Date of Submission

Yidi Hou
Program Manager
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110

Phone: 651-653-8512
Fax: 651-407-1975

Date Prepared: July 02, 2025

Device Name

Trade Name:	MammoSTAR Biopsy Site Identifier
Classification Name:	Implantable Clip
Regulation Number:	21 CFR 878.4300
Common/Usual Name:	Tissue Marker
Product Codes:	NEU
Device Class:	II
Review Panel:	General and Plastic Surgery

Predicate Device:

Trade Name:	[Trade Name] Preloaded Tissue Marker Device
510(k) Number:	K100994
Classification Name:	Implantable Clip
Regulation Number:	21 CFR 878.4300
Common/Usual Name:	Tissue Marker
Product Codes:	NEU
Device Class:	II
Review Panel:	General and Plastic Surgery

Device Description

MammoSTAR Biopsy Site Identifier is a sterile, single use tissue marker consisting of pyrolytic carbon coated zirconium oxide discrete marker e that is visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound and Magnetic Resonance Imaging (MRI) incorporated into lyophilized BiomarC Delivery Gel. MammoSTAR is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

Indication for Use

MammoSTAR Biopsy Site Identifier is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Technological Characteristics and Performance

The subject device MammoSTAR Biopsy Site Identifier is substantially equivalent to the predicate device K100994 regarding the fundamental technologies, intended use and indications for use. Both are single-use tissue markers. There are no changes to the device's technological characteristics. The device remains identical to the predicate devices and is therefore considered equivalent. No new performance data is required to support this Change Being Effected (CBE) determination.

Substantial Equivalent

The subject device has the same intended use and indications for use as the predicate device. They also have the same fundamental scientific technology in that they are all sterile, single use implantable devices composed of pyrolytic carbon coated zirconium oxide markers embedded in lyophilized betal-glucan.

The subject and predicate devices are identical in design, material composition, manufacturing process, and sterilization method (gamma irradiation). The only notable difference is an added contraindication (do not use in the presence of local and systemic infection). Since there is no change to the device, no testing has been submitted, referenced, or relied upon to establish substantial equivalence. The product remains unchanged in all respects.

The table below further summarizes the similarities and difference between the subject and predicate devices.

Characteristic	Proposed Device	Predicate Device	Comparison
Trade Name	MammoSTAR Biopsy Site Identifier	MammoSTAR Tissue Marker	
510(k) Number	K251748	K100994	
510(k) Holder	Carbon Medical Technologies, Inc.	Carbon Medical Technologies, Inc.	**Same**
Indication For Use	To radiographically mark soft tissue at the surgical site 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**
Contraindication	Do not use in the presence of local and systemic infection.	None	**New contraindication added**

Characteristic	Proposed Device	Predicate Device	Comparison
Use	Single Use	Single Use	**Same**
Marker Visualization Modalities	Visible on kV X-ray, CT, CBCT, mammography, ultrasound, and Magnetic Resonance Imaging (MRI).	Visible on kV X-ray, CT, CBCT, mammography, ultrasound, and Magnetic Resonance Imaging (MRI).	**Same**
Radiopaque Marker Material	Pyrolytic Carbon Coated Zirconium Oxide	Pyrolytic Carbon Coated Zirconium Oxide	**Same**
Device body contact category	Implant device, tissue, permanent	Implant device, tissue, permanent	**Same**
Patient-Contact Marker Material	Pyrolytic Carbon	Pyrolytic Carbon	**Same**
Pyrolytic Carbon Coating Vendor	Carbon Coating Technologies St. Paul, MN USA	Carbon Coating Technologies St. Paul, MN USA	**Same**
Pyrolytic Carbon Coating Hardness	≥ 200 DHP by Vicker's harness test	≥ 200 DHP by Vicker's harness test	**Same**
Pyrolytic Carbon Coating Thickness	≥ .0005 inch	≥ .0005 inch	**Same**
Pyrolytic Carbon Coating visual appearance	No discoloration or uncoated areas when viewed at 7X min.	No discoloration or uncoated areas when viewed at 7X min.	**Same**
Pyrolytic Carbon Coating Microstructure	The outer .0005 inches of coating on the marker will be 95% free from inclusions, banding and cracks.	The outer .0005 inches of coating on the marker will be 95% free from inclusions, banding and cracks.	**Same**
Patient-Contact Marker Carrier Composition	Lyophilized Beta Glucan	Lyophilized Beta Glucan	**Same**
Glucan Chemical Composition	≥ 80% (1-3), (1-4) β-D glucan ≤ 2.5 % protein and nitrogen impurity < 6% moisture < 4% ash ≤ 15% other carbohydrates ≤ 0.5% preservative	≥ 80% (1-3), (1-4) β-D glucan ≤ 2.5 % protein and nitrogen impurity < 6% moisture < 4% ash ≤ 15% other carbohydrates ≤ 0.5% preservative	**Same**
Glucan Concentration	3% Glucan Gel - Lyophilized	3% Glucan Gel - Lyophilized	**Same**

Characteristic	Proposed Device	Predicate Device	Comparison
Glucan Material Vendor	Bio-Industrial Opportunities Edmonton, AB Canada	Bio-Industrial Opportunities Edmonton, AB Canada	**Same**
MR Environment Safety and Compatibility	MR Conditional. Labeling specifies the full conditions (3-Tesla or less, etc.) under which the device can be safely scanned.	MR Conditional. Labeling specifies the full conditions (3-Tesla or less, etc.) under which the device can be safely scanned.	**Same**
Sterile barrier packaging	BOPA/Polyethylene/Foil with chevron feature	BOPET/Polyethylene/Foil with chevron feature	**Substantially Equivalent**
Sterility Assurance Level (SAL)	$> 1\times10^{-6}$	$> 1\times10^{-6}$	**Same**
Sterilization Method	Gamma Irradiation	Gamma Irradiation	**Same**
Contract sterilizer, Sterilization process	STERIS Isomedix Libertyville, IN USA Services Gamma Irradiated	STERIS Isomedix Libertyville, IN USA Services Gamma Irradiated	**Same**
Sterilization Dose range	25.0 – 35.0 kGy	25.0 – 35.0 kGy	**Same**
Pyrogen testing per Kinetic Chromogenic LAL	< 0.5 EU/mL	< 0.5 EU/mL	**Same**
Shelf Life	60 months	6 months	**Shelf-life has been verified to 60 months.**

Tests performed to evaluate and compare technological and performance characteristics:

Non-clinical performance data **-** The subject device remains identical to the predicate devices and is therefore considered equivalent. No new non-clinical performance data is required to support this Change Being Effected (CBE) determination.

Clinical performance data – no clinical study is deemed necessary to support this Change Being Effected (CBE) determination since substantial equivalence has been sufficiently demonstrated.

Conclusion

The device remains unchanged and is therefore as safe, effective, and performs as well as the legally marketed predicate device. The subject device is substantially equivalent to the predicate device.