Carbon Medical Technologies Inc.
℅ Mr. Eric Furlich
Director - R&D and Regulatory Affairs
1290 Hammond Road
ST. PAUL MN 55110

June 10, 2021

Re: K211590
Trade/Device Name: [Trade Name] Fiducial Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: May 20, 2021
Received: May 24, 2021

Dear Mr. Furlich:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K211590

Device Name
[Trade Name] Fiducial Marker

Indications for Use *(Describe)*
The [Trade Name] Fiducial Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic body radiosurgery (SBRT) and radiotherapy target localization.

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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"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 – K211590

Submitter's Name, Address and Date of Submission

Eric Furlich
Director – R&D and Regulatory Affairs
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110
Phone: 651-653-8512
Fax: 651-407-1975

Submitted: 18 May 2021

Device Name

Trade Name:	[Trade Name] Fiducial Marker
Common Name:	Fiducial Marker
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050
Product Code:	IYE

Predicate Device

BiomarC Fiducial Marker (K110772)
Preloaded Tissue Marker (K100994)

Indication for Use

The [Trade Name] Fiducial Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic body radiosurgery (SBRT) and radiotherapy target localization.

Device Description

The [Trade Name] Fiducial Marker is a sterile, pyrogen free, single patient use, pyrolytic carbon coated zirconium oxide discrete marker incorporated into lyophilized glucan gel carrier that is visible on kV X-ray, CT, CBCT, mammography, ultrasound, and Magnetic Resonance Imaging (MRI).

Technological Characteristics and Performance

The technological characteristics are equivalent to the predicate devices. A Failure Modes and Effects Analysis (FMEA) was performed in order to assess the risks associated with the modifications introduced. A biocompatibility, visibility, MR safety / compatibility and sterilization and packaging / shelf-life adoption evaluation confirmed that the modified device, [Trade Name] Fiducial Marker, was substantially equivalent to the predicate devices.