Carbon Medical Technologies Announces FDA 510(k) Clearance of BiomarC Restore

(October 19, 2021) - Carbon Medical Technologies, Inc. a St. Paul based company that designs, develops, and manufactures pyrolytic carbon-based implantable medical devices is proud to announce U.S. Food and Drug Administration (FDA) 510(k) clearance of BiomarC Restore, a lumpectomy cavity fiducial marker. BiomarC Restore is a pyrolytic carbon coated discrete marker that is embedded into lyophilized glucan as a means of stabilizing the marker within the surgical cavity. The BiomarC Restore lumpectomy cavity fiducial marker is intended to be placed into the body during an open surgical procedure to accurately mark tissue and act as a distinctive reference point during stereotactic body radiotherapy (SBRT) and radiotherapy target localization.

"Combining the technology of lyophilized glucan and pyrolytic carbon coating, BiomarC Restore is a natural addition to Carbon Medical Technologies product portfolio," said Stephanie Kent, President and Chief Executive Officer at Carbon Medical Technologies, Inc. "BiomarC Restore's natural, non-feral magnetic ceramic composition will compliment Carbon Medical Technologies BiomarC Fiducial Marker product line and will allow us to meet the specialized needs of our customers following a lumpectomy procedure."

"BiomarC Restore is designed to provide patients with comfort and physicians with confidence by positioning and maintaining the marker in the surgical cavity created during a lumpectomy procedure," said Tina Wittchow, Vice President Professional Services and Chief Operating Officer. "BiomarC Restore will serve as a mark of distinction to ensure that the lumpectomy site can be identified by a patient's physician on various imaging modalities to assist with radiation therapy treatment."

BiomarC Restore will be available in 2022. For more information about the product please visit our website www.carbonmed.com.

About Carbon Medical Technologies, Inc.

Carbon Medical Technologies, Inc. (CMT) is a privately held company formed in 1994 to design, develop, and manufacture permanent human implantable products utilizing pyrolytic carbon. Carbon is a naturally occurring element in the human body. As a result, pyrolytic carbon is not recognized by the human body as foreign, thus rendering it ideal as a permanent implant material. CMT operates a fully functional pyrolytic carbon coating facility and has developed multiple FDA approved, cleared to market, and CE Marked products. Currently, the pyrolytic carbon coating technology is incorporated into BiomarC implantable tissue markers developed for biopsy site marking, the BiomarC fiducial marker product line for radiation therapy treatment planning, and an injectable bulking agent called Durasphere, which is used for the treatment of stress urinary incontinence in women, and additional indications outside of the US. CMT also provides product development, contract manufacturing, and regulatory consulting for medical device companies. The company is a medical device manufacturer with ISO 13485 certified and cGMP compliant quality systems, maintains three different sterilization method validations, and does final product assembly and packaging in an ISO Class 7 clean room environment.