GT Medical Technologies
℅ Ms. Jessica Newhard
Regulatory Affairs Specialist
1809 S Holbrook Lane, Suite 107
TEMPE AZ 85281

January 23, 2020

Re: K190839
Trade/Device Name: GammaTile™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXK
Dated: December 20, 2019
Received: December 23, 2019

Dear Ms. Newhard:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190839

Device Name
GammaTile™

Indications for Use *(Describe)*
GammaTile is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms

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."

III. 510(k) Summary K190839

Table 1. Tabular Summary of 510 (k)

Submitter	GT Medical Corporation
Address	1809 S Holbrook Drive Suite 107 Tempe, AZ 85281
Telephone Number	480-276-8609
Contact Person	Jessica Newhard Regulatory Affairs Specialist jnewhard@gtmedtech.com
Date of Preparation	December 20, 2019
Device Trade Name	GammaTile™
Device Common Name	Radionuclide Brachytherapy Seeds
Device Classification Name	Radionuclide Brachytherapy Source (per 21CFR §892.5730)
Device Regulation Number	892.5730
Product Code	KXK
Predicate Device(s)	Predicate: GammaTile that is the subject of this submission is substantially equivalent to GammaTile as described in 510(k) K190296.
Predicate Product Code	KXK
Predicate Regulation Number	892.5730
Product Description	GammaTile is a device intended for the treatment of intracranial neoplasms which uses cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is designed to provide "adjuvant" radiation therapy – therapy to eliminate any remaining neoplastic cells – to patients who require surgical resection of brain neoplasms. GammaTile is positioned within the resection cavity immediately after surgical excision of the brain neoplasm to deliver radiation therapy to any neoplastic cells that remain in proximity of the resection cavity.

Indication for Use statement compared to currently marketed predicate device	The Indication for Use is being revised to include initial treatment of intracranial neoplasms. The currently marketed indication for use is: "GammaTile is intended to deliver radiation therapy (brachytherapy) in patients with recurrent intracranial neoplasms" The proposed indication for use statement is: "GammaTile is indicated as a treatment for patients with newly diagnosed malignant

	intracranial neoplasms and patients with recurrent intracranial neoplasms"
Patient Population	This premarket submission expands the patient population from patients requiring radiation therapy after excision for recurrent intracranial neoplasms to include patients requiring radiation therapy after excision of newly diagnosed malignant intracranial neoplasms.
Statement of Technological Characteristics	The technological characteristics of the proposed device, GammaTile, are identical to those of the predicate, GammaTile as described in 510(k) K190296
Assessment of Non-clinical Performance Data	No changes have been made to the technological characteristics of the proposed device since clearance of the primary predicate device (K190296). The indication expansion proposed does not change the anatomical site of the indication but expands the target population to include newly diagnosed patients with malignant intracranial neoplasms. An assessment of dosimetry to organs at risk using GammaTile in recurrent intracranial neoplasms has been completed. The assessment resulted in a determination the cumulative radiation dose delivered to the OARs was within ranges acceptable in clinical practice.
Conclusion Drawn from Testing	No additional testing was completed. The data obtained from the case studies suggest that GammaTile therapy adds no additional risk to the proposed patient population.

Safety and Effectiveness	To ensure that the devices are safe and effective, all finished products must meet all acceptance criteria required by the product specification before distribution. The required testing is defined in documented procedures that conform to the product design specifications.