GT Medical Technologies
℅ Jessica Newhard
Regulatory Affairs and Quality Assurance Manager
1809 S Holbrook Lane, Suite 107
TEMPE AZ 85281

November 9, 2022

Re: K221539
Trade/Device Name: GammaTile®
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXK
Dated: October 7, 2022
Received: October 11, 2022

Dear Jessica 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,

Julie Sullivan -S

Julie Sullivan, Ph.D.
Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K221539

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.

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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."

I. 510(k) Summary

Table 1. Tabular Summary of 510 (k) K221539

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 and Quality Assurance Manager jnewhard@gtmedtech.com
Date of Preparation	November 4, 2022
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: K190839 GammaTile (Indications for Use) Reference Device: K150825 DuraMatrix Onlay Plus
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.

Indications for Use Statement	GammaTile is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms.
Indication for Use statement compared to currently marketed predicate device	No change is being requested to the indication for use statement within this submission.
Patient Population	No change is being requested to the patient population within this submission. GammaTile is intended for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms.
Statement of Technological Characteristics	The change to materials, specifically the change in collagen carrier of the subject device, has been assessed to ensure it has technological characteristics equivalent to the predicate device. Biocompatibility testing was performed and demonstrated that GammaTile subject device maintains an equivalent biocompatibility profile as the predicate device. A collagenase study was performed on the subject device, predicate device and reference device which demonstrated that the bioresorption timeframe is similar between the predicate device material and the subject device material. A simulated use study was performed on the subject device and determined that, under simulated use conditions, exposure to radioactive seeds does not impact the performance characteristics of the subject device. A risk assessment has been completed to assess whether the change to materials has any impact on safety or effectiveness of the device. The risk/change analysis resulted in a determination of no new risks.

Assessment of Non-clinical Performance Data	The subject device has been assessed to ensure it has technological characteristics equivalent to the predicate device. Biocompatibility testing was performed and demonstrated that GammaTile manufactured with the GTMT Collagen (subject device) maintains an equivalent biocompatibility profile as the predicate device. A collagenase study was performed on the e-beam and EO sterilized GTMT Collagen and demonstrated that the bioresorption timeframe is similar between e-beam and EO sterilized predicate collagen carrier material and e-beam and EO sterilized GTMT Collagen. A simulated use study was performed and determined that, under simulated use conditions, exposure to radioactive seeds does not impact the performance characteristics of the subject device. A risk assessment has been completed to assess whether the GTMT Collagen carrier has any impact on safety or effectiveness of the device. The risk/change analysis resulted in a determination of no new risks.
Conclusion Drawn from Testing	Biocompatibility testing demonstrated that the predicate device and subject device have similar biocompatibility profiles. The collagenase testing concluded that the GTMT Collagen performed similarly to the predicate collagen carrier material which demonstrates that the subject device will have a similar bioresorption profile to the predicate device. In addition, the simulated use study showed no difference in performance between the predicate device and the subject device. Therefore, based on the results from the previous implant studies conducted on the predicate device and the reference device (equivalent to GTMT Collagen), the similar bioresorption profile, an equivalent

	manufacturing process of the finished GammaTile device, and the performance testing results, it was determined that the subject device has equivalent technological characteristics to the predicate.
Safety and Effectiveness	To ensure that the devices are safe and effective compared to the predicate, 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. The similar performance characteristics demonstrated through simulated use testing and the collagenase study provide evidence that the GTMT Collagen will continue to function as a three-dimensional spacer preventing the seeds from direct tissue contact to avoid overdosing and as a multi-seed carrier providing even spacing between adjacent seeds. The GTMT collagen does not impact the safety or effectiveness of the GammaTile device in comparison to the predicate.