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

March 13, 2019

Re: K190296
Trade/Device Name: GammaTile™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXK
Dated: February 8, 2019
Received: February 11, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K190296

Device Name
GammaTile

Indications for Use *(Describe)*
GammaTile is intended to deliver radiation therapy (brachytherapy) in 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.

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Food and Drug Administration
Office of Chief Information Officer
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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

K190296

Table 1. Tabular Summary of 510 (k)

Submitter	GT Medical Technologies
Address	1809 S Holbrook Lane Suite 107 Tempe, AZ 85281
Telephone Number	480-276-8609
Contact Person	Jessica Newhard Regulatory Affairs Specialist jnewhard@gtmedtech.com
Date of Preparation	February 12, 2019
Device Trade Name	GammaTile™
Device Common Name	Radionuclide Brachytherapy Seeds
Device Classification Name	Radionuclide Brachytherapy Source (per 21CFR §892.5730)
Predicate Device(s)	Primary Predicate: GammaTile that is the subject of this submission is substantially equivalent to GammaTile as described in 510(k) 180515
Product Description	GammaTile is a device intended for the treatment of recurrent 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 recurrent 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.
Statement of Intended Use compared to currently marketed predicate device	There is no change to the intended use or indications for use compared to the currently marketed predicate. The intended use of the proposed device is identical to the legally marketed device:

	GammaTile is intended to deliver radiation therapy (brachytherapy). The indication for use is identical to the legally marketed device: GammaTile is intended to deliver radiation therapy (brachytherapy) in patients with recurrent intracranial neoplasms.
Patient Population	Patients requiring radiation therapy after excision for recurrent 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) K180515
Assessment of Non-clinical Performance Data	No significant changes have been made to the technological characteristics of the proposed device since clearance of the primary predicate device (K180515). In addition, the intended use and indication for use remains the same between the proposed device and the predicate device (K180515). A risk/change analysis has been completed to assess whether the changes proposed had any impact on safety or effectiveness of the device. The risk/change analysis resulted in a determination of no new risk and validation testing confirmed these changes did not raise new safety concerns.
Conclusion Drawn from Testing	Test results confirmed that the changes made have no impact to product safety or efficacy and introduce no new risks.
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.