Isoray Medical Inc.
℅ Mr. Bill Joy
Director, RA/QA
350 Hills Street, Suite 106
RICHLAND WA 99354

July 6th, 2018

Re: K180515
Trade/Device Name: GammaTile™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: June 11, 2018
Received: June 12, 2018

Dear Mr. Joy:

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. 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.

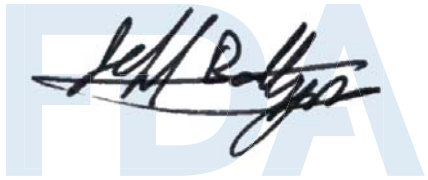
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,



for
Robert Ochs, 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)*
K180515

Device Name
GammaTile

Indications for Use *(Describe)*
GammaTileTM 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.

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3.0 510(k) Summary Required by 21 CFR § 807.92(c)

3.1 **Submitter**: IsoRay Medical, Inc.

3.2 **Address**: 350 Hills Street, Suite 106
Richland, WA 99354-5411

3.3 **Telephone and Fax Numbers**: 509-375-1202
(Fax) 509-375-3473

3.4 **Contact Person**: Bill Joy,
Director, Quality Assurance & Regulatory Affairs
bjoy@isoray.com

3.5 **Date of preparation of this Summary**: February 23, 2018

3.6 **Device Name, Regulatory and Classification Information**:

3.6.1 **Trade Name**: GammaTile™

3.6.2 **Common Name**: Radionuclide Brachytherapy Seeds

3.6.3 **Classification Name**: Radionuclide Brachytherapy Source, (Per 21 CFR §892.5730).

3.7 **Marketed device to which equivalence is claimed**: The GammaTile™ that is the subject of this submission are substantially equivalent to the Proxcelan™ (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands as described in 510(k) K092136 (SE 08/07/2009).

3.8 **Product Description**: The GammaTile™ is a device, intended for the treatment of recurrent intracranial neoplasms that uses cesium-131 radioactive sources embedded in a collagen matrix. The 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.

3.9 **Statement of intended use compared to the currently marketed predicate device**: The intended use of the proposed device is as follows:

> GammaTile™ is intended to deliver radiation therapy (brachytherapy).

This is equivalent to the intended use of the legally marketed predicate device, Proxcelan™ (Cesium-131) Implant Devices,

Model PL-5 – Cs-131 Preloaded Braided Strands as described in 510(k) K092136 (SE 08/07/2009).

3.10 **Patient Population**: Patients requiring radiation therapy after excision for recurrent intracranial neoplasms.

3.11 **Statement of Technological Characteristics**: The technological characteristics of the proposed device, GammaTile™, are identical to those of the predicate, Model PL-5, Preloaded Braided Strands as described in 510(k) K092136.

3.12 **Assessment of Non-Clinical Performance Data**: The proposed and predicate devices are substantially equivalent based on the results of simulated clinical use testing, characterization of the radionuclide source and source spacing during bench testing.

3.13 **Conclusion Drawn from Testing**: Based on the results of the analysis and verification/validation testing performed on the proposed device it has been demonstrated that: 1) GammaTile™ can consistently be built to design specifications, 2) GammaTile™ is biocompatible and can be routinely sterilized, 3) GammaTile™ structural integrity is maintained through the duration of therapeutic life of the cesium-131 radiation sources.

3.14 **Safety and Effectiveness**: To ensure that the devices are safe and effective, all finished products are tested and must meet all acceptance criteria required by specifications before distribution. The testing required for release includes, but is not limited to testing for proper assembly and seed spacing, apparent activity, external contamination, sterility, pyrogens, and labeling. The required testing is defined in documented procedures that conform to the product design specifications.