Isoray Medical, Inc.
% Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Parkway SE, Suite 3740
ATLANTA GA 30080

March 8, 2023

Re: K202267
Trade/Device Name: Sirius MRI Markers, Cs-131 Preloaded Strands with Sirius MRI Markers in 18 Gauge Needles
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXK

Dear Grace Powers:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 12/31/2020. Specifically, FDA is updating this SE Letter as an administrative correction with a correction to the 510(k) summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lora D. Weidner, OHT8: Office of Radiological Health, Ph: (240) 402-6424, Lora.Weidner@fda.hhs.gov.

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.03.08 06:09:19 -05'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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

Isoray Medical, Inc.
% Ms. Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Parkway SE, Suite 3740
ATLANTA GA 30080

December 31, 2020

Re: K202267
Trade/Device Name: Cs-131 Implant Devices with Sirius™ Markers
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXK
Dated: December 10, 2020
Received: December 11, 2020

Dear Ms. Powers:

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,

Michael D. O'Hara 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)*

K202267

Device Name
Cs-131 Implant Devices with SiriusTM Markers

Indications for Use *(Describe)*
The Isoray Medical, Inc. Cs-131 Implant Devices with SiriusTM MRI Markers are indicated for the treatment of malignant prostatic disease. These devices may be used as a primary treatment or in conjunction with other modalities. The MRI Markers are used to facilitate the anatomical localization of seeds after they have been implanted.

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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Section 5
510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Cs-131 Implant Devices with MRI Markers Traditional 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Isoray Medical, Inc.
350 Hills Street
Suite 106
Richland, WA US 99354

Submission Contact: Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
Tel: 404-931-8730

Submission Date: August 10, 2020

Subject Device: Trade Name: Cs-131 Implant Devices with Sirius™ Markers
Common Name: Radionuclide brachytherapy source
Regulation: 21 CFR §892.5730
Regulatory Classification: 2
Product Code**:** KXK

Predicate Device: Legally marketed device to which substantial equivalence is claimed:
Proxcelan™ (Cesium-131) Implant Devices, Multiple Configurations (K092458)
Reference Device: Sirius™ MRI Marker NS (K171487)

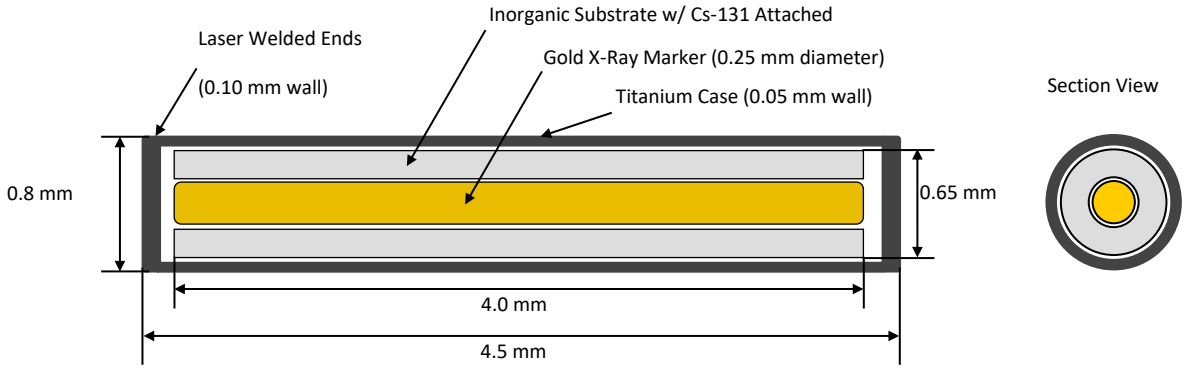
Device Description
The Isoray Medical, Inc. Cs-131 Implant Devices with Sirius™ Markers are a combination of two commercially available devices: The Isoray Medical Cs-131 Implant Devices, and the Sirius™ MRI Markers. They come in two configurations and listed below:

- Isoray Medical, Inc. Cs-131 PL-7 Preloaded Strands with Sirius™ Markers
- Isoray Medical, Inc. Cs-131 PL-8 Preloaded Strands with Sirius™ Markers in 18G Needles

The Sirius™ MRI Markers combined with the Isoray Cesium-131 Implant Devices will be used to facilitate the anatomical location of seeds after they have been implanted in the prostate of a patient with confirmed prostatic malignancy.

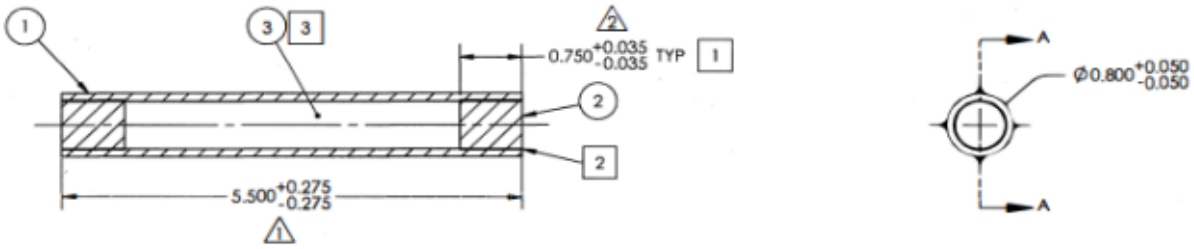
The Cs-131 Implant Devices are a small, cylindrical, sealed source that consists of a welded pure titanium capsule containing the low energy gamma (x-ray) emitting isotope, Cesium-131 (Cs-131), adsorbed onto an internal inorganic substrate. The external seed dimensions are 4.5 mm length and 0.8 mm diameter and the only patient-contacting material is commercially pure titanium. A schematic diagram of the internal configuration of the Isoray Medical, Inc. Cs-131 Implant Devices that are used in both the subject devices is shown in the schematic below.

Figure 1: Cs-131 Brachytherapy Seed Schematic



The Sirius™ MRI markers consist of a sealed polyether ether ketone (PEEK) polymer capsule containing a cobalt chloride: N-Acetylcysteine solution. The Sirius™ MRI Marker is a component device indicated as an accessory for use in conjunction with brachytherapy seed carrier sleeves and radionuclide brachytherapy seeds containing one of the following isotopes: Iodine-125, Palladium-103 or Cesium-131. The Sirius™ MRI Markers combined with the Isoray Cesium-131 Brachytherapy Seeds will be used to facilitate the anatomical location of seeds after they have been implanted. A schematic diagram of the Sirius™ MRI Markers that are used in both the subject devices is shown in the schematic below.

Figure 2: Sirius™ MRI Markers



The spacers are used to maintain the exact locations and separation distances between the seeds as indicated on the treatment plan prepared by the physician or medical physicist. They are made of PLA/PGA copolymer and are absorbable. The spacer length is variable since it is a function of how many seeds are required by the patient treatment plan. The spacers are 0.8mm in diameter.

The Cs-131 Implant Devices with MRI Markers comes in two (2) configurations as listed in the table below.

Table 3: Isoray Medical, Inc. Cs-131 Implant Devices s with MRI Markers
Additional Product Offerings

Product Reorder Number	Product Description
PL-7	Cs-131 Preloaded Strands with Sirius™ Markers
PL-8	Cs-131 Preloaded Strands with Sirius™ Markers in 18G Needles

The seeds, spacers, and Sirius™ MRI markers are arranged in a precise pattern in order to maintain the exact locations and separation distances between the seeds as indicated on the treatment plan prepared by the physician or medical physicist. There are no product specific guidance documents or product specific standards for brachytherapy seeds. The subject devices are EtO sterilized and are a single-use device.

Indications for Use

The Isoray Medical, Inc. Cs-131 Implant Devices with Sirius™ Markers are indicated for the treatment of malignant prostatic disease. These devices may be used as a primary treatment or in conjunction with other modalities. The MRI Markers are used to facilitate the anatomical localization of seeds after they have been implanted.

Technological Characteristics

The Cs-131 Brachytherapy Seeds with Sirius™ Markers has similar technological characteristics as the predicate device, Cs-131 Implant Device cleared via K092458. Both devices have similar indications for use. The seeds are identical to the predicate device and the spacers are identical to the reference device. All the devices are composed of biocompatible materials. Additionally, they are both provided sterile in identical packaging for single use.

	Subject Device: Cs-131 Implant Devices with Sirius™ Markers	**Predicate Device: Cs-131 Implant Devices**	**Reference Device: Sirius™ MRI Markers**	**Comparison**
Name	Cs-131 Implant Device with Sirius™ MRI Markers	CS-131 PRELOADED STRANDS, MODEL PL-1, CS-131 PRELOADED STRANDS IN 18 GAUGE NEEDLES, MODEL PL-2	Sirius™ MRI Markers	N/A
Manufacturer	Isoray Medical, Inc.	Isoray Medical, Inc.	C4 Imaging, LLC	N/A
Product Code	KXK	KXK	KXK	Identical
Regulation Number	21 CFR 892.5730	21 CFR 892.5730	21 CFR 892.5730	Identical
Device Classification Name	Source, Brachytherapy, Radionuclide	Source, Brachytherapy, Radionuclide	Source, Brachytherapy, Radionuclide	Identical
Device Classification	Class II	Class II	Class II	Identical

	Subject Device: Cs-131 Implant Devices with Sirius™ Markers	**Predicate Device: Cs-131 Implant Devices**	**Reference Device: Sirius™ MRI Markers**	**Comparison**
Indication for Use	The Isoray Medical, Inc. Cs-131 Implant Devices with Sirius™ MRI Markers are indicated for the treatment of malignant prostatic disease. These devices may be used as a primary treatment or in conjunction with other modalities. The MRI Markers are used to facilitate the anatomical localization of seeds after they have been implanted.	The Isoray Medical, Inc. Cesium-131 Implant Devices are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.), and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. These devices may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.	The Sirius™ MRI Marker is a component device indicated as an accessory for use in conjunction with carrier sleeves and radionuclide brachytherapy seeds containing one of the following isotopes: Iodine-125, Palladium-103 or Cesium-131. The Sirius MRI Marker NS is intended to facilitate the anatomical localization of seeds after they have been implanted in the prostate of a patient with confirmed prostatic malignancy. It is intended to be imaged under MRI within sixty (60) days of implantation. The Sirius MRI marker NS is supplied non-sterile and will need to be	Similar- The indications for use are a combination of the indications from the predicate and reference device. The subject device indication includes the indication from the predicate device seeds limited to the prostate as the MRI Markers are limited to use in the prostate with brachytherapy seed carriers containing the Cesium-131 isotope. The statement that the MRI Markers are used for localization of the seeds after implant was also included in the subject device indication.

	Subject Device: Cs-131 Implant Devices with Sirius™ Markers	**Predicate Device: Cs-131 Implant Devices**	**Reference Device: Sirius™ MRI Markers**	**Comparison**
			sterilized by the end-use using either gamma radiation or ethylene oxide.	
Principle of Operation	Brachytherapy is performed by implanting radiation sources directly into the tissue to be treated. This provides a much higher tumor dose to be delivered, while sparing normal surrounding tissue. The Sirius™ MRI Marker is a component of Isoray's Cesium-131 Implant devices that is intended to facilitate the anatomical localization of the brachytherapy seeds after they have been implanted. The operation of the Cs-131 Implant Devices with Sirius™ MRI Markers (subject device) is the same as the predicate device.	Brachytherapy is performed by implanting radiation sources directly into the tissue to be treated. This provides a much higher tumor dose to be delivered, while sparing normal surrounding tissue.	The Sirius™ MRI Marker is intended to facilitate the anatomical localization of the brachytherapy seeds after they have been implanted.	The subject, predicate have a similar principle of operation. The subject device can be used to visualize the location due to the addition of the MRI markers (reference device).
Condition of Use	Single Use Only	Single Use Only	Single Use Only	Identical
Rx or OTC	Prescription Only	Prescription Only	Prescription Only	Identical

	Subject Device: Cs-131 Implant Devices with Sirius™ Markers	Predicate Device: Cs-131 Implant Devices	Reference Device: Sirius™ MRI Markers	Comparison
Materials of Construction	Seeds: Titanium Spacers: PLA/PGA copolymer Sleeve: 5/95 PLA/PGA Sleeve Needle: Stainless Steel Bone wax: Product code MTJ MRI Markers: PEEK	Seeds: Titanium Spacers: PLA/PGA copolymer Sleeve: 5/95 PLA/PGA Sleeve Needle: Stainless Steel Bone wax: Product code MTJ	MRI Markers: PEEK	The seeds, spacers, sleeve, needles and bone wax in the subject device and predicate device are identical. The MRI marker materials are identical to the reference device.
Device dimensions	Seed: 0.8mm diameter, 4.5mm length Spacer: 0.8mm diameter, 2.5mm, 5.5mm and 10.0 mm length MRI Marker: 0.8mm diameter, 5.5mm length	Seed: 0.8mm diameter, 4.5mm length Spacer: 0.8mm diameter, 2.5mm, 5.5mm, 10.0mm length	MRI Marker: 0.8mm diameter, 5.5mm length	The MRI marker that is being added is the same diameter and length as the current spacer.
Packaging	Tray within a breather bag pouch	Tray within a breather bag pouch	Not applicable – Sold in bulk as an accessory	The subject and predicate devices have identical packaging.
Device Package Contents	• PL-7: Cs-131 Preloaded Strands with Sirius™ Markers • PL-8: Cs-131 Preloaded Strands with Sirius™ Markers in 18G Needles	• PL-1: Cs-131 Preloaded Strands • PL-2: Cs-131 Preloaded Strands in 18 Gauge Needles	Not applicable – Sold in bulk as an accessory	The contents of the subject device and predicate device are identical with the exception of the MRI markers included in the subject device.
Sterilization	EtO validated cycle	EtO validated cycle	Not applicable – Sold non-sterile as an accessory	The subject and predicate devices are both EtO sterilized.

Performance Data

No performance data testing was performed as each of the components has been previously cleared for this intended use. No additional biocompatibility test was performed as biocompatibility evaluation was conducted for each of the components in previous regulatory clearances. The brachytherapy seeds, Sirius™ MRI markers and spacers are considered implants.

The finished device is sterilized via a validated EtO sterilization cycle and provide a Sterility Assurance Level (SAL) of 1 x 10^{-6}. Sterilization is performed by Isoray Medical, Inc. Validation of the device will be performed in accordance with ISO 11135:2014 *Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*. The half-cycle method was used was validation. The validation method and dose range is in accordance with ISO 11135:2014 *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Conclusion

The Cs-131 Implant Devices with Sirius™ Markers is substantially equivalent to the legally marketed predicate device as demonstrated by similar intended use, similar technologies and does not raise different questions of safety and effectiveness.