DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2017

C4 Imaging, LLC
% Stephen Goldner, J.D.
President
Regulatory Affairs Associates
4761 Tara Court
WEST BLOOMFIELD MI 48323

Re: K171487
Trade/Device Name: Sirius MRI Marker NS
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: July 28, 2017
Received: July 31, 2017

Dear Mr. Goldner:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Attachment 1

Revised Indications for Use (Form FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171487

Device Name
Sirius MRI Marker NS

Indications for Use *(Describe)*
The Sirius MRI Marker NS 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 (125I), Palladium 103 (103Pd) or Cesium 131 (131Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

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 sterilized by the end-user using either gamma radiation or ethylene oxide.

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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510(k) Summary

[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

Submitted by:	C4 Imaging, LLC 196 West Ashland Street Suite 109 Doylestown, PA 18901 USA Phone: +1 (609) 933-5895 Email: abright@c4imaging.com
Contact Person:	Stephen J. Goldner, JD, RAC Regulatory Affairs Associates, LLC 4761 Tara Court West Bloomfield, MI 48323 USA Phone: +1 (248) 515-0097 Fax: +1 (313) 557-4200 Email: sgoldner@regaffairs.net
Date Prepared:	July 28, 2017

Device Name

Trade Name:	Sirius MRI Marker NS
Common Name(s):	Accessory to applicator and accessory to brachytherapy source

Classification

Regulation:	21 CFR §892.5730
Class:	Class II
Product Code:	KXK
Classification Name:	Radionuclide brachytherapy source

Predicate Devices

MRI Marker	K131689	C4 Imaging

Device Description

C4 Imaging's Sirius MRI Marker NS consists of a sealed polyether ether ketone (PEEK) polymer capsule containing a cobalt chloride:N-Acetylcysteine solution. It is used as an accessory to radionuclide sources (seeds) during prostate brachytherapy procedures. The length of the capsule is 5.5 mm and the diameter is 0.8 mm.

The Sirius MRI Marker NS will be supplied non-sterile and will be sterilized by the end-user using ethylene oxide or gamma radiation.

Indications

The Sirius MRI Marker NS 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 (^{125}I), Palladium 103 (^{103}Pd) or Cesium 131 (^{131}Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

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 sterilized by the end-user using either ethylene oxide or gamma radiation.

Comparison to Predicate Devices

The proposed device, Sirius MRI Marker NS, is a seed spacer intended to maintain spacing between radioactive seeds when delivered by a preloaded seeding needle.

The manufacturing process for the Sirius MRI Marker NS is the same as the previously cleared MRI Marker (K131689) except for the sterilization method and site. The MRI Marker was supplied sterile. The sterilization method used was gamma radiation (Cobalt 60). The Sirius MRI Marker NS will be supplied non-sterile and will be sterilized by the end-user using ethylene oxide or gamma radiation (Cobalt 60).

The Sirius MRI Marker NS is supplied in packs of up to 250 units within a primary container, which is contained within a secondary protective barrier. The pack is supplied within an outer box.

The predicate device, MRI Marker, is provided sterile in packs of 100 units within a primary container, which is contained within a secondary sterility barrier. The sterile pack is supplied within an outer protective box.

Conclusion

There are no differences between the proposed device Sirius MRI Marker NS and the predicate device with regard to dimension, composition of the fill solution, and manufacturing process of the marker itself that would affect the safety or effectiveness of the proposed device.

The differences in the packaging process are due to the Sirius MRI Marker NS being supplied non-sterile and held in bulk until order fulfillment. The container/closure system for the bulk packaged markers is the same as the system for the original MRI Marker, 4 mL amber, borosilicate glass vial with a black polypropylene cap.

Supplying the marker as nonsterile to be sterilized by the end user and the addition of ethylene oxide sterilization as an alternative sterilization method should not affect the performance of the marker.