C4 Imaging LLC
% Mr. Andrew Bright
President and CEO
196 West Ashland Street
DOYLESTOWN PA 18901

April 27, 2018

Re: K180069
Trade/Device Name: HDR MRI Lumen Marker
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 2, 2018
Received: April 4, 2018

Dear Mr. Bright:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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)*
K180069

Device Name
HDR MRI Lumen Marker

Indications for Use *(Describe)*

The HDR MRI Lumen Marker is indicated as an accessory for use with FDA Market Cleared remote controlled radionuclide applicator systems that are used to treat tumors that are indicated for treatment with high dose rate (HDR) brachytherapy. The HDR MRI Lumen Marker is indicated for temporary placement in HDR applicator lumens.

The HDR MRI Lumen Marker is intended to facilitate the identification of HDR applicator treatment lumens. It is intended to be non-patient contacting and only placed in applicators that are designed to prevent patient tissue or bodily fluids accessing the inner lumen.

Once placed in an HDR applicator lumen the HDR MRI Lumen Marker is intended to be imaged with MRI. It is removed after MR imaging and prior to the placement of a radioactive source. The HDR MRI Lumen Marker is intended for use in a single patient and can be used more than once if required for a single course of treatment in a single patient.

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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Section 02 510(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: Andrew Bright
Date Prepared:	December 29, 2017

Device Name

Trade Name:	HDR MRI Lumen Marker
Common Name(s):	HDR applicator lumen marker

Classification

Regulation:	21 CFR §892.5700
Class:	Class II
Product Code:	JAQ
Classification name:	Remote controlled radionuclide applicator system accessory

Predicate Device

Interstitial Ring CT/MR Applicator Set	K091154	Nucletron

Device Description

The HDR MRI Lumen Marker is a sealed high-density polyethylene (HDPE) tube containing a cobalt chloride N-Acetylcysteine saline solution. The HDPE tube is up to 350.0 mm in length and 1.0 mm in diameter, with the distal 19.0 mm of the tube accommodating a HDPE sealing plug. The distal end of the device is provided with an attached HDPE end-cap for handling. This end cap is approximately 3.0 mm in length.

The HDR MRI Lumen Marker is an accessory to remote controlled high dose rate (HDR) radionuclide applicator systems and facilitates the identification of lumens within MRI compatible HDR brachytherapy applicators. Each HDR MRI Lumen Marker is supplied with a silicone stopper designed to hold the device in place once fully inserted into an applicator.

Indications

The HDR MRI Lumen Marker is indicated as an accessory for use with FDA Market Cleared remote controlled radionuclide applicator systems that are used to treat tumors that are indicated for treatment with high dose rate (HDR) brachytherapy. The HDR MRI Lumen Marker is indicated for temporary placement in HDR applicator lumens.

The HDR MRI Lumen Marker is intended to facilitate the identification of HDR applicator treatment lumens. It is intended to be non-patient contacting and only placed in applicators that are designed to prevent patient tissue or bodily fluids accessing the inner lumen.

Once placed in an HDR applicator lumen the HDR MRI Lumen Marker is intended to be imaged with MRI. It is removed after MR imaging and prior to the placement of a radioactive source. The HDR MRI Lumen Marker is intended for use in a single patient and can be used more than once if required for a single course of treatment in a single patient.

Comparison to Predicate Devices

C4 Imaging's HDR MRI Lumen Marker is an accessory to high dose rate (HDR) brachytherapy remote controlled radionuclide applicator systems and is intended to be used to identify treatment lumens in FDA approved MR compatible HDR applicators once the applicator has been placed in the treatment site. It is placed in a HDR applicator lumen and imaged with MRI. It is removed prior to treatment.

The Interstitial Ring CT/MR Applicator Set (Nucletron BV - K091154) is identified as the principal predicate device to which the HDR MRI Lumen Marker is substantially equivalent (SE). The Interstitial Ring CT/MR Applicator Set is a legally marketed device that has the same intended uses, and the same technological characteristics as proposed for the HDR MRI Lumen Marker.

The Interstitial Ring CT/MR Applicator Set includes a polymer tube (Teflon) that can be filled with an appropriate fluid that can be clearly visualized on MRI. The HDR MRI Lumen Marker has essentially the same technological characteristics in that it's comprised of a polymer tube (HDPE) that is filled with a fluid that is clearly visible on MRI. Both devices are placed in HDR applicators that have been pre-inserted into the target treatment area of a patient and are MR imaged to facilitate a physician and dosimetrist identifying the location of the treatment source(s) during subsequent therapy. Neither devices are intended to come into direct contact with a patient and both are placed in the interior of applicators that are designed to prevent tissue or bodily fluids entering the inner lumen. Both devices are removed after MR imaging and before treatment begins.

Conclusion

The HDR MRI Lumen Marker is substantially equivalent to the MRI line marker that is a part of the previously cleared Interstitial Ring CT/MR Applicator Set (K091154). There are no differences that would affect the safety or effectiveness of the proposed device.