U.S. FOOD & DRUG ADMINISTRATION

ViewRay, Incorporated
% Sean Delaney
Sr. Director, Regulatory Affairs and Quality Assurance
815 E. Middlefield Road
MOUNTAIN VIEW CA 94043

February 20, 2019

Re: K181989
Trade/Device Name: MRIdian Linac System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: January 22, 2019
Received: January 24, 2019

Dear Sean Delaney:

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

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)*
K181989

Device Name
MRIdian Linac System

Indications for Use *(Describe)*
The MRIdian Linac system, with magnetic resonance imaging capabilities, is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

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 6: 510(k) Summary

The information below is provided for the modified MRIdian Linac system, following the format of 21 CFR 807.92.

1. Address and Contact Information:

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Mountain View, California, 94043

Contact Name: Sean A. Delaney

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Date Summary was prepared: July 13, 2017

2. Name of Device: MRIdian Linac System

Trade/Proprietary Name: MRIdian Linac System

Common or Usual Name:

Accelerator, Linear, Medical;

System, Nuclear Magnetic Resonance Imaging

Regulation description/number:

21 CFR 892.5050

- Device: Accelerator, Linear, Medical
- Regulation Description: Medical charged-particle radiation therapy system

21 CFR 892.1000

- Device: System, Nuclear Magnetic Resonance Imaging
- Regulation Description: Magnetic resonance diagnostic device

Product Codes: IYE; LNH. Class II.

Device classification name: Accelerator, Linear, Medical; System, Nuclear Magnetic Resonance Imaging

3. Substantial Equivalence

Predicate device: MRIdian Linac System - K170751

Reference device: MRIdian Linac System – K162393

4. Description of the Device

The MRIdian Linac system (K162393; K170751) delivers ionizing radiation using a magnetic resonance imaging system (MRIS) unit for image guidance. This submission describes an optional change only to the treatment planning and delivery imaging workflows of the predicate MRIdian Linac system.

ViewRay developed the following additional imaging modalities for use during MRIdian Linac system treatment planning and delivery workflows:

1. Introduction of a Treatment Delivery Computer Unit (TDCU) to increase treatment imaging reconstruction and display speed in excess of eight frames per second along with improved cine image resolution used for target tracking.
2. The predicate MRIdian Linac system supports the import of MR images obtained from a separate imaging system for use in treatment planning. In addition to importing additional MR images, the proposed MRIdian Linac system is also able to generate the following additional MR sequences for use during planning, positioning, and treatment delivery workflows:
    a. Turbo Spin Echo (TSE) pulse sequence family including Half Fourier Acquisition Single Shot Turbo Spin Echo (HASTE) and Diffusion Prepared Turbo Spin Echo (DP-TSE) which enables the following contrast protocols:
        i. T1-weighted (spin-lattice; magnetization in the same direction as the static magnetic field);
        ii. T2-weighted (spin-spin; magnetization transverse to the static magnetic field); and
        iii. Diffusion-Weighted Imaging (DWI) with ability to generate Apparent Diffusion Coefficient (ADC) maps to overlay and register to other images.
    b. True Fast Imaging (TRUFI) pulse sequence with radial sampling enabling higher speed imaging during treatment delivery.

The currently marketed MRIdian Linac system integrates radiation therapy with simultaneous magnetic resonance imaging of soft tissues to provide optimal alignment, adaptation, and tracking. These proposed changes to the existing system described in this section aim to improve MR imaging speed and quality and provide additional image contrast modalities.

5. Intended Use Statement

The MRIdian Linac system, with magnetic resonance imaging capabilities, is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

6. Indication for Use Statement

The MRIdian Linac system, with magnetic resonance imaging capabilities, is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

7. Substantial Equivalence

ViewRay has demonstrated that the proposed MRIdian Linac system performs in a substantially equivalent manner to the predicate system (K162393; K170751).

8. Technological Characteristics

The cleared MRIdian Linac system (K162393; K170751) is an Image-Guided Radiation Therapy System (IGRT) that uses a 6 MV linear accelerator radiotherapy system to deliver ionizing radiation while using a magnetic resonance imaging system (MRIS) unit for image guidance in real-time. The MRIdian Linac system has equivalent functionality when employing the proposed imaging modalities described in this submission.

Like the current MRIdian Linac system (K162393; K170751) the proposed system consists of three primary subsystems:

1. The Treatment Planning and Delivery System (TPDS, initially cleared under K102915) modified only to support the new user interface changes during use of the new MR sequences during treatment planning and delivery workflows and support treatment image reconstruction on updated Treatment Delivery Computer Unit (TDCU) computer hardware as a replacement for the 'Services' computer in the predicate device;
2. The Magnetic Resonance Imaging System (MRIS) which has been updated to include additional imaging pulse sequences; and
3. The Radiation Therapy Delivery System (RDS) modified only to condense the equipment room footprint by combining the pulse modulator, power distribution unit, and the linac control cabinet into one pulse modulator cabinet and to support the software interfaces changes described in this submission.

In both systems these three subsystems are designed to operate concurrently for accurate targeted administration of radiation therapy.

The MRIdian Linac system with the changes proposed in this section is otherwise unchanged and functions as designed in the original predicate system so that the imaging and radiotherapy fields of view coincide permitting imaging of the patient at the radiotherapy isocenter before and during treatment.

The Treatment Planning and Delivery System (TPDS initial clearance K102915)

The Treatment Planning and Delivery System software (TPDS) is capable of assisting the clinician in creating treatment delivery and QA plans for the MRIdian Linac system. The TPDS includes clinician tasks for reviewing, prescribing, tracking, and correcting the course of patient treatment. The software system has two major roles: radiotherapy treatment planning, and radiotherapy treatment delivery.

ViewRay modified the TPDS user interface to support treatment planning and delivery workflows when using the new MR sequences and support treatment image reconstruction on updated the Treatment Delivery Computer Unit (TDCU) computer hardware. The TDCU replaces the Services computer used by the predicate MRIdian Linac system in order to gain efficiencies when reconstructing MR images. There have been no changes to the Monte Carlo dose calculation algorithm. TPDS is otherwise unchanged from the predicate device (K162393; K170751) other than changes described in **Section 12**.

Magnetic Resonance Imaging System (MRIS)

The Magnetic Resonance Imaging System (MRIS) unit incorporates an original equipment manufacturer (OEM) version of the Siemens MAGNETOM Avanto system combined with a 0.35T superconducting magnet, gradient coil, and radio frequency (RF) coil system, redesigned to be compatible with radiation therapy delivery. The MRIS system hardware remains unchanged from the current MRIdian Linac system (K162393; K170751).

The MRIS subsystem software has been updated to include additional imaging sequences described in **Section 12.** The MRIS software is otherwise unchanged from the predicate device (K162393; K170751).

The Radiation Therapy Delivery System (RDS)

The Radiation Therapy Delivery System (RDS) of both the predicate MRIdian Linac system (K162393; K170751) and the proposed system described in this Section consist of a linear accelerator unit mounted on a ring gantry. By design, the radiation isocenter is in the middle of the imaging field of view, permitting imaging at the radiotherapy isocenter before and during therapy. The RDS of both systems include:

- Linear Accelerator;
- Gantry and Base Subsystem;
- 138-leaf Multi-leaf Collimator (MLC) (K170751);
- Patient Handling System;
- Rotating Shim Gantry;
- Radiation Therapy Control System (RTCS) and Console;
- Magnetic and RF shielding sleeve technologies;
- Linac Control Cabinet; and
- RF components required for linac functionality.

Equipment Room Update

ViewRay developed a revised design of the Pulse Modulator to reduce the physical footprint within the system equipment room by combining the pulse modulator, the Power Distribution Unit (PDU), and Linac Control Cabinet (LCC) into one cabinet. This change does not alter the performance of the system. Refer to **Section 12** for details of this change.

The RDS is otherwise unchanged from the predicate device (K162393; K170751) except for modifications necessary to support software changes associated with the new options described in this section.

The proposed MRIdian Linac system functions in a substantially equivalent manner to the predicate device when employing the new MR imaging modalities described in this submission. **Table 6-1** presents a comparison of specifications for the predicate and proposed MRIdian Linac systems.

Table 6-1: Predicate Device Comparison Chart

Attribute	Cleared Device (K162393; K170751)	Device with Changes
Imaging Settings	1. PLAN—imaging for planning or virtual simulation 2. POSITION—imaging for patient positioning 3. TREAT—imaging for target position monitoring	Same
MR Physical Characteristics: Bore Diameter Spherical Volume (DSV)	700 mm 500 mm	Same
MRI Frequency Field Strength Field of View Field Homogeneity Field Stability	14.7 MHz 0.345 T 500 mm < 25 ppm measured over 450 mm DSV ≤ 0.1 ppm/hr	Same
3D Imaging Volumes in cm 3D Imaging Resolution in cm 2D Imaging Planes in cm 2D Imaging Resolution in cm Geometric Accuracy Signal to Noise Temporal Integrity Imaging Dose per treatment	RL x AP x HF Min 20 x 27 x 29 Max 54 x 48 x 54 Min 0.075 x 0.075 x 0.15 Max 0.3 x 0.3 x 0.3 AP x HF Min. 27 x 27 Max 45 x 35 0.35 x 0.35 5,7, or 10 2 mm over 35 cm FOV 1 mm over 20 cm FOV 30 0.01s or better None	Same

Imaging Pulse Sequences: • T1 weighted • T2 weighted • Diffusion Weighted Imaging (DWI)	Can be imported from an alternative imaging device.	Can be acquired by the proposed MRIdian Linac system or imported from an alternative imaging device.
Imaging During Radiation Therapy Delivery	The MRI system supports the acquisition of a single plane (axial, sagittal, or coronal) in 4 frames per second and up to three planes in 2 frames per second with an in-plane resolution of 2.5 x 2.5 mm or less	The MRI system supports the acquisition of a single plane (axial, sagittal, or coronal) in 8 frames per second and up to three planes in 2 frames per second with an in-plane resolution of 2.5 x 2.5 mm or less
Localization/ Positioning	The MRI system acquires and reconstructs a 3D volume for Positioning to a maximum of 540 mm x 540 mm x 480 mm FOV with an in-plane resolution of 3.0 x 3.0 mm or less. These volumes are acquired with an acquisition time of less than 60 seconds.	Same
Planning Volumes	540 mm x 465 mm x 430 mm FOV with an in-plane resolution of 1.5 x 1.5 mm or less.	Same
Multi-Channel RF System	Body coil SNR is ≥ 12; Uniformity is ≥ 60% 12 Channel Torso Coil SNR is ≥ 30 (Sagittal, Transversal); SNR is ≥ 25 (Coronal); Uniformity is ≥ 50% 10 Channel Head/Neck Coil SNR is ≥ 30 (Sagittal, Transversal); SNR is ≥ 25 (Coronal); Uniformity is ≥ 50%	Same with the addition of: 4 Channel Head Coil SNR is ≥ 30 (Sagittal, Transversal); SNR is ≥ 25 (Coronal); Uniformity is ≥ 50%

9. Summary of Performance Testing

Design Verification testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards presented below.

The imaging capabilities of the proposed MRIdian Linac system showed substantial equivalence to the predicate system (K162393; K170751). Testing executed on the system verified conformance to design requirements and ensured all identified risks and hazards were mitigated, and demonstrated conformance to relevant safety standards. The MRIdian Linac system described in this premarket notification passed all verification testing, and the system conformed to all applicable sections of the standards presented below.

Software verification testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The MRIdian Linac software is considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the MRIdian Linac system which verified the system complies with the IEC 60601-1-2 EMC standard and continues to meet IEC 60601-1 safety standards.

Name	Description
IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) ed. 3.1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 ed. 4.0	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-33: 2010 (Third Edition) + A1: 2013 + A2: 2015 ed. 3.2	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 60601-2-1:2009, AMD1:2014 2014 ed. 3.1	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
IEC/EN 60976:2007 ed. 2.0	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
IEC 60601-1-6:2013 ed. 3.1	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 61217:2011 ed. 2.0	Radiotherapy Equipment - Coordinates, Movements & Scales
IEC 62083:2009 ed. 2.0	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
IEC 62304:2006 (First Edition) + A1:2015 ed. 1.1	Medical device software - Software life cycle processes
IEC 62366:2007, A1:2014 ed. 1.1	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10993-1:2009 ed. 4.0	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

10. Conclusion

Verification testing of the MRIdian Linac system with proposed enhance imaging modalities demonstrated that the device met established standards and design requirements. System performance was found to be substantially equivalent in function to the predicate device MRIdian Linac system (K162393; K170751). Therefore, the proposed MRIdian Linac system performs in a substantially equivalent manner as the predicate device when using the enhanced imaging modalities described in this submission.