December 14, 2021

ViewRay, Incorporated
% Mr. Sean Delaney
Senior Advisor, Continuous Improvement & Development Strategy
815 E. Middlefield Road
MOUNTAIN VIEW CA 94043

Re: K212958
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: September 14, 2021
Received: September 16, 2021

Dear Mr. 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/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,

, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212958

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 6: 510(k) Summary

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

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Premarket Notification 510(k) Summary

As Required by 21 CFR 807.92

510(k) Number:	K212958
Product Name:	MRIdian Linac System
Date Prepared:	September 13, 2021
Submitter:	ViewRay Incorporated 815 E. Middlefield Road Mountain View, CA 94043 USA
Primary Contact Person:	Sean Delaney (650) 252-0969 sdelaney@viewray.com
Secondary Contact Person:	Elizabeth Osuna (408) 431-1046 eosuna@viewray.com
Common or Usual Name:	Medical Linear Accelerator
Regulatory Name:	21 CFR 892.5050
Classification Name:	Medical charged-particle radiation therapy system
Product Code:	IYE, LNH
Primary Predicate Device:	MRIdian Linac System K181989

Device Description

The MRIdian Linac system is an image-guided radiation therapy (IGRT) system that uses a 6 MV linear accelerator radiotherapy system to deliver ionizing radiation while using a magnetic resonance imaging system for image guidance in real time. The MRIdian consists of the Treatment Planning and Delivery System (TPDS), Magnetic Resonance Imaging System (MRIS) and the Radiation Therapy Delivery System (RDS). These three subsystems are designed to operate concurrently for accurate targeted administration of radiation therapy.

Intended Use

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.

Indication for Use

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.

Significant Differences

- The Treatment Planning and Delivery System modified with a redesigned Treatment Delivery subsystem (TDS) and the same Treatment Planning subsystem (TPS) modified only to support the new TDS implementation;
- The Magnetic Resonance Imaging System (MRIS) which has been updated to support an end-of-life replacement of the MR control system software (Siemens Avanto Dot) and include additional support for an updated head (receive) coil; and
- The Radiation Therapy Delivery System (RDS) modified only to support the TDS software interfaces changes.

Summary of Technological Characteristics

Device Characteristic	Predicate Device	Subject Device	Comparison
Radiation Source			
Nominal Beam Energy	6 MV	6 MV	Same
Isocenter Distance	90 cm	90 cm	Same
Nominal Dose Rate	600 MU/min	600 MU/min	Same
Collimation			
Radiation Field Sizes	2 mm x 4.15 mm to 27.4 x 24.1 cm projected by isocenter	2 mm x 4.15 mm to 27.4 x 24.1 cm projected by isocenter	Same
Primary Collimation Method	138-leaf MLC	138-leaf MLC	Same
Resolution at isocenter	Each leaf projects with a nominal width of 0.83 cm at 90 cm SAD. The double- stack MLC uses an offset between the top and bottom stack to achieve a nominal effective leaf width of 0.415 cm at 90 cm SAD.	Each leaf projects with a nominal width of 0.83 cm at 90 cm SAD. The double- stack MLC uses an offset between the top and bottom stack to achieve a nominal effective leaf width of 0.415 cm at 90 cm SAD.	Same
Collimation Transition Time	MLC leaf speed of 4 cm/s at isocenter	MLC leaf speed of 4 cm/s at isocenter	Same
Imaging			
Energy/Type	0.345 Tesla superconducting MRI	0.345 Tesla superconducting MRI	Same

Device Characteristic	Predicate Device	Subject Device	Comparison
Field of View Size	50 cm diameter spherical volume (DSV)	50 cm diameter spherical volume (DSV)	Same
Contrast Resolution	Complies with IEC 60601-2-33	Complies with IEC 60601-2-33	Same
Spatial Resolution	Volume scans: Min 0.075 x 0.075 x 0.15 Max 0.3 x 0.3 x 0.3 Ciné scans: Slice thickness 5, 7, or 10 mm One plane: Sagittal Pixel size: 0.24 x 0.24 0.35 x 0.35	Volume scans: Min 0.075 x 0.075 x 0.075 Max 0.3 x 0.3 x 0.3 Ciné scans: Slice thickness 5, 7, or 10 mm One, two, or three planes: Axial, sagittal, or coronal Pixel size: 0.13 x 0.13; head 0.20 x 0.20; body 0.24 x 0.24; body 0.35 x 0.35; body	Volume scans: Minimum longitudinal resolution from 0.15 to 0.75. Ciné scans: Pixel size: 0.13 x 0.13; head 0.20 x 0.20; body
Dose	None	None	Same
Physical Geometry			
Bore size	The system has a diameter of 70 cm nominal	The system has a diameter of 70 cm nominal	Same
Room Dimensions	The MRIdian Linac minimum vault size with finishes is	The MRIdian Linac minimum vault size with finishes is	Same

Device Characteristic	Predicate Device	Subject Device	Comparison
	19' 2" wide by x 24' 8" long [5.9 m x 6.93 m]. The minimum finished ceiling height over the footprint of system is 9' 6" [2.9 m] to allow for clearance of system covers which are 9' 4"	19' 2" wide by x 24' 8" long [5.9 m x 6.93 m]. The minimum finished ceiling height over the footprint of system is 9' 6" [2.9 m] to allow for clearance of system covers which are 9' 4"	
Patient Couch – Degrees of Freedom	3D shifts and shifted values are within ± 0.1 cm in each dimension	3D shifts and shifted values are within ± 0.1 cm in each dimension	Same
Patient Surface - Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Same

Performance Data

The MRIdian Linac System was tested according to the FDA Quality System Regulation (21 CFR §820). Test results demonstrate that the device conforms to design specifications and meets the needs of the intended users, including assuring risk mitigations were implemented and functioned properly. Software testing was performed and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Standards

The MRIdian Linac System conforms to the following regulatory standards including FDA recognized standards and references additional standards as applicable.

Rec. #	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
19-4	ANSI AAMI	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-8	ANSI AAMI IEC	60601-1-2:2014	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
	EC	60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
12-285	IEC	60601-2-1 Edition 3.0	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
12-295	IEC	60601-2-33 Ed. 3.2 b:2015	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
12-267	IEC	61217 Edition 2.0 2011-12	Radiotherapy equipment - Coordinates, movements, and scales
12-217	IEC	62083 Edition 2.0 2009-09	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
5-114	ANSI AAMI IEC	62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Rec. #	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
	IEC	62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
5-89	IEC	60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
12-253	IEC	60976 Edition 2.0 2007-10	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
2-258	ANSI AAMI ISO	10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	ISO	10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Bench Testing

The performance data demonstrate that the MRIdian Linac System is as safe and effective and performs as well as the predicate device.

Clinical Testing

No animal or clinical tests are being submitted to establish substantial equivalence with the predicate device.

Conclusion

The MRIdian Linac System is substantially equivalent to the predicate device. The intended use and indications for use are the same. The major technological characteristics are substantially equivalent to the predicate device, and the differences do not raise new questions of safety and effectiveness. The results of testing as well as conformance to relevant safety standards demonstrate that MRIdian Linac System meets the safety and performance criteria and is substantially equivalent to the predicate device.