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

February 24, 2017

ViewRay Incorporated
% Sean A. Delaney
Senior Manager, Regulatory Affairs
2 Thermo Fisher Way
OAKWOOD VILLAGE OH 44146

Re: K162393
Trade/Device Name: The ViewRay (MRIdian) Linac System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 14, 2017
Received: February 16, 2017

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. 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 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 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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K162393

Device Name
The ViewRay (MRIdian) Linac System

Indications for Use *(Describe)*
The ViewRay (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 ViewRay (MRIdian) Linac system, following the format of 21 CFR 807.92.

1. Address and Contact Information:

ViewRay Incorporated

2 Thermo Fisher Way

Oakwood Village, OH 44146

Contact Name: Sean A. Delaney

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Fax: (650) 625-9187

E-mail: sdelaney@viewray.com

Date Summary was prepared: January 13, 2017

2. Name of Device: ViewRay (MRIdian) Linac system

Trade/Proprietary Name: MRIdian Linac system

Common or Usual Name: Accelerator, Linear, Medical

Regulation description/number:

Medical charged-particle radiation therapy system

21 CFR §892.5050, Class II

Product Code: IYE

Device classification name: Accelerator, Linear, Medical

3. Predicate Device to claim substantial equivalence

ViewRay (MRIdian) System for Radiation Therapy – K111862

ViewRay Treatment Planning and Delivery System – K102915

TrueBeam Radiotherapy Delivery System – K111106 (Reference Device)

4. Description of the Device

The MRIdian Linac system delivers ionizing radiation using a magnetic resonance imaging system (MRIS) unit for image guidance and a 6MV linear accelerator to deliver radiation therapy. The system is designed so that the imaging and radiotherapy fields of view coincide permitting imaging of the patient at the radiotherapy isocenter before and during treatment. The MRIdian Linac system is used with the ViewRay Treatment Planning and Delivery System (TPDS) (K102915). As with the predicate MRIdian System (K111862), the MRIdian Linac System consists of three primary subsystems:

1. The Treatment Planning and Delivery System (TPDS)
2. The Magnetic Resonance Imaging System (MRIS)
3. The Radiation Therapy Delivery System (RDS)

These three subsystems are designed to operate concurrently for accurate targeted administration of radiation therapy.

5. Intended Use Statement

The ViewRay (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 ViewRay (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

The MRIdian Linac system submission demonstrates substantial equivalence to the predicate MRIdian device (K111862).

8. Technological Characteristics

The predicate ViewRay (MRIdian) system for radiation therapy (K111862) is an Image-Guided Radiation Therapy System (IGRT) that uses a magnetic resonance imaging (MRI) unit for image guidance with a three-headed Cobalt-60 (Co-60) radiotherapy system. Like the predicate MRIdian system, the MRIdian Linac system delivers ionizing radiation using a magnetic resonance imaging system (MRIS) unit for image guidance. The primary difference between the MRIdian system and the MRIdian Linac system is in the ionizing radiation source. The MRIdian Linac system differs from the predicate only by the changes required to support a device modification to change the output Energy Type of the system from Cobalt 60 to a linear accelerator.

While there are differences in the MV photon energy spectra of the two output Energy Types (or sources), ViewRay previously demonstrated in K111862 that the Cobalt 60 ionizing radiation dose distributions delivered to the patient by the predicate MRIdian system was substantially equivalent to the 6 MV ionizing-radiation dose distributions delivered by its predicate. The predicate in K111862 was the Varian Trilogy MX (K092871) linac based therapy system. The Varian TrueBeam (K111106) which also has the Varian Trilogy MX as its predicate also provides the same output energy type as the MRIdian Linac, an unflattened 6 MV linac beam. The MRIdian Linac system replaces the three Cobalt-60 sources utilized by the predicate MRIdian system with a single 6 MV Linear Accelerator to

supply ionizing radiation similar to the single linac of the Varian TrueBeam (K111106) and the shared Varian Trilogy MX (K092871) predicate.

The MRIdian Linac system functions in a manner directly analogous to the functions provided by the predicate MRIdian system. Both systems use images obtained from MRI for planning. Although the MRIdian Linac system uses a different source of radiation (linac), both systems are intended for use for radiation therapy and are used by the same user population.

The MRIdian Linac system employs two well-established technologies, MRI and radiotherapy delivery using linac with treatment planning functions to provide comprehensive image guided radiation therapy solution. The MRIdian Linac system is substantially equivalent to the imaging and therapy technologies used in the predicate MRIdian system (K111862). Both systems are used by trained clinicians to provide stereotactic radiosurgery and precision radiotherapy to patients.

Performance specifications of the MRIdian Linac and predicate device are noted in the table below:

Feature	Cleared Device K111862	Device with Change K162393
Radiation Source	Cobalt-60 Sources (qty. 3)	6MV Linear Accelerator
Beam	2.0 cm dia. Cobalt 60 Gamma Ray Source, 1.332 & 1.172 MeV	6 MV Bremsstrahlung X- Rays produced by Linear Accelerator
Max Dose Rate	600 cGy/min. total 200 cGy/min.per head (at installation) at Dmax at 105cm isocenter for a 10.5 cm x 10.5 cm field (three sources are utilized)	600 cGy/min. at Dmax at a 90 cm isocenter for a 10 cm x 10 cm field (Single Source)
Static Dose Accuracy	90% of the points evaluated in a treatment volume pass a relative gamma criteria of 3%/3mm and a high dose, low gradient absolute point measurement is within 5% of the planned dose (per AAPM TG 119 based on the recommendations of Palta et al.).	90% of the points evaluated in a treatment volume pass a relative gamma criteria of 3%/3mm and a high dose, low gradient absolute point measurement is within 5% of the planned dose (per AAPM TG 119 based on the recommendations of Palta et al.).
Moving Target Dose Accuracy	Dose delivery on a moving target is consistent within ≤ |2 %| to that of a stationary target with the use of real time tumor tracking (RealTarget).	Dose delivery on a moving target is consistent within ≤ |2 %| to that of a stationary target with the use of real time tumor tracking (RealTarget).

Collimation Range of MLC collimated beam size	Field shaping, Multi Leaf Collimator(MLC) Quantity of 3 1.05cm x 1.05cm to 27.3cm x 27.3cm projected at isocenter	Field shaping, Multi Leaf Collimator(MLC) Quantity of 1 0.72 cm x 1.43 cm to 25.71 cm x 25.71 cm projected at isocenter
Number of leaves per MLC	60	60
MLC material	Tungsten Alloy	Tungsten Alloy
Isocenter distance	105 cm	90 cm
Isocenter accuracy	0.5mm radius (1 mm diameter)	0.5mm radius (1 mm diameter)
<u>Minimum Room Dimensions</u> Height/Length/Width <u>Environment</u> Line Voltage Ambient Room Temp. Relative Humidity Power Distribution Isolation	 2.9 m x 7.6 m x 5.9 m 380-480V 65 °F to 72 °F 40 to 60% Transformer	 2.9 m x 7.6 m x 5.9 m 480V 65 °F to 72 °F 40 to 60% Transformer
Radiation Head Shielding	Depleted Uranium and Tungsten Alloy shield with stainless steel shell, 15,000 Curies max. capacity	Lead, Tungsten Alloy, and Steel shielding
Source control mechanism	Redundant timers controlling pneumatically driven linear source movement mechanisms	Redundant ion chambers and dose monitoring cards
Radiation Leakage when OFF	In the fully shielded BEAM OFF position, measured at survey points, is in accordance with NCRP #102.	Not applicable, no leakage when OFF
Radiation Transmission through head	With the source in the fully exposed BEAM ON position is less than 0.1% of the primary beam.	Less than 0.1% of the primary beam.
Method of IMRT	MLC based cone-beam delivery	MLC based cone-beam delivery
Gantry	Ring Gantry, collision with patient not possible	Ring Gantry, collision with patient not possible
Motion synchronized treatment	Yes	Yes

Integrated imaging for planning, positioning, gating	Magnetic resonance imaging system	Magnetic resonance imaging system
MR Physical Characteristics Bore Diameter Diameter Spherical Volume (DSV)	 700 mm 500 mm	 700 mm 500 mm
Patient table degrees of freedom	3 translational	3 translational
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	14.7 MHz 0.345 T 500 mm < 25 ppm measured over 450 mm DSV ≤ 0.1 ppm/hr
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	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	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

Temporal Integrity Signal to Noise Dose per treatment	0.01s or better 30 None	0.01s or better 30 None
Treatment Planning and Delivery System Dose Algorithm (K102915) Dose Output Modeling Dose Display	Monte Carlo Dose Computation Radiation Source Model for Cobalt photons. Dose output modeled with beam-on time Display of Cobalt delivery parameters	Monte Carlo Dose Computation Radiation Source Model for Bremsstrahlung X-Rays, fundamental radiation-transport algorithm is unchanged. Dose output modeled with monitor units Display of Linac delivery parameters

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 and radiation therapy capabilities of the MRIdian Linac system showed substantial equivalence to the predicate device. 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 required 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 complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 EMC standard.

Name	Description
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) ed 3.1	General requirements for basic safety and essential performance
IEC 60601-1-2:2007 ed. 3.0	Electromagnetic compatibility (EMC)
IEC 60601-2-33:2015 ed. 3.2	MR for Medical Diagnosis
IEC/EN 60601-2-1:2009 ed. 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
IEC/EN 60976:2007 ed. 2.0	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
IEC 60601-1-6:2013 ed. 3.1	Usability
IEC 61217:2011 ed. 2.0	Radiotherapy Equipment - Coordinates, Movements & Scales
IEC 62083:2009 ed. 2.0	Radiotherapy Treatment Planning Systems
EN 62304:2006 ed. 1.0	Software Lifecycle Processes
EN 62366:2014 ed. 1.1	Usability
ISO 10993-1:2009	Biocompatibility

10. Conclusion

Verification testing of the MRIdian Linac system demonstrated that the device met established standards and design requirements. System performance was found to be equivalent in function to the predicate MRIdian device. Therefore, the MRIdian Linac system is substantially equivalent to the indicated predicate device (MRIdian System K111862).