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VIEWRAY INCORPORATED

The future of radiotherapy.

2 Thermo Fisher Way, Oakwood Village Ohio 44146

Premarket Notification [510(k)] Summary
The ViewRay™ System for Radiation Therapy

The following information is provided following the format of 21 CFR §807.92.

Submitter's Name:

ViewRay Incorporated
2 Thermo Fisher Way
Oakwood Village, OH 44146

Contact Name: Janice Brownlee
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Date: 17th May 2012

Proprietary Name: ViewRay™ System

Classification Name: Radionuclide Radiation Therapy System
21 CFR §892.5750, Class II
Product Code (classification): IWB

Common/Usual Name: The ViewRay™ System for Radiation Therapy

Predicate Device: Trilogy Mx™ Radiotherapy Delivery System K092871, 11/30/2009

Device Description:

The ViewRay™ System for Radiation Therapy is a single medical device that combines a magnetic resonance imaging system for image guidance, with a cobalt-60 radiation delivery system. 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. These imaging and radiation delivery systems are designed to operate together as the ViewRay System, for accurate, targeted administration of radiation therapy. The ViewRay System is used with the ViewRay Treatment Planning and Delivery System (TPDS) (K102915, FDA clearance 1/12/11).

The magnetic resonance imaging system (MRIS) of the ViewRay System can be used by the clinician to perform three (3) different functions before and during the treatment of a patient. A trained clinician may choose to perform all, some, or none of the functions. These 3 functions are:

- Treatment planning – the images from the ViewRay MRIS can be used to perform pre-treatment and on-table planning.
- Patient positioning – Fast pilot or planning volumetric images can be used to position the patient.

- Treatment gating (soft tissue tracking)– If the prescribing clinician employs this feature during therapy, planar MR images (in a single plane or in 3 planes) are taken continuously during therapy delivery, to control the beam based on anatomy motion.

The ViewRay radiation delivery system (RDS) consists of:

- Radioactive cobalt-60 sources
- Source shielding heads and movement mechanism
- Gantry and base
- Multi-leaf collimators
- Radiation therapy control system
- User console

The sealed cobalt-60 sources are housed in source-shielding heads made of tungsten alloy and depleted uranium encased with stainless steel. The heads are mounted on a ring gantry located between the gap in the MRIS magnets. The sources can be positioned for therapy (BEAM ON), standby (BEAM HOLD) and shielding (BEAM OFF) by the source movement mechanism. The beams from the sources are shaped to conform to the target using double focused multi-leaf collimators. The radiation therapy interfaces with the radiation treatment planning, imaging, gating, and dose calculation functions by means of the radiation therapy control system (RTCS). This system is the central point of control and is designed to provide fail-safe operation of the ViewRay System. The RTCS includes the Radiation Therapy Controller (RTC) and the Auxiliary Controller (AUXC). The AUXC provides secondary monitoring of the ViewRay System safety functions in the event of an RTC failure. The ViewRay System records patient information, treatment plans, dose administered during each fraction, the accumulated dose, imaging data, and system performance during treatment.

Statement of Intended Use: The ViewRay 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.

Statement of Indications for Use: The ViewRay 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.

Technological Characteristics:

The ViewRay System functions in a manner directly analogous to the functions provided by the Varian Medical Systems' Trilogy Mx™ Radiotherapy Delivery System. Both the ViewRay and Varian Systems can use images obtained from CT, PET or MRI for planning. Although the Varian System uses a different technology for obtaining images during delivery of treatment (CT vs. MRI) and a source of radiation (linac vs. cobalt-60), both systems are intended for use for radiation therapy, and are used by the same user population. By eliminating the radiation exposure of a CT scan and using MRI instead, the ViewRay System can allow continuous imaging to take place during administration of the radiation therapy,

thereby keeping the target area in view and minimizing unintended radiation of healthy surrounding tissue.

The ViewRay System employs two well-established technologies, MRI and radiotherapy delivery using cobalt-60 with treatment planning functions to provide a comprehensive IGRT solution. The ViewRay System is substantially equivalent to the imaging and therapy technologies used in the Varian System, CT and linear accelerator. All of these technologies were well established in the marketplace prior to being used together in IGRT systems. Both the ViewRay and Varian systems are used by trained clinicians to provide stereotactic radiosurgery and precision radiotherapy to patients.

Summary of Performance Testing:

Design Verification testing was performed on the imaging and radiation therapy capabilities of the ViewRay System to show substantial equivalence to the predicate device. Additionally, testing was executed on the System to verify conformance to design requirements, to ensure all identified risks and hazards were mitigated, and to demonstrate conformance to relevant standards. The ViewRay System described in this premarket notification passed all verification testing, and the System conformed with all applicable sections of IEC 60601-1 (2.0 Edition), IEC 60601-2-33 (3.0 Edition) and IEC 60601-2-11 (2.0 Edition)

Conclusion:

The ViewRay System for radiation therapy shares many of the technological features and characteristics with its predicate, the Trilogy Mx™ System. Verification testing of the ViewRay System demonstrated that the device met established standards and design requirements for image guided radiation therapy equipment. System performance was found to be equivalent in function to the predicate device. Therefore, the ViewRay System is substantially equivalent to the indicated predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Janice Brownlee
VP Regulatory Affairs and Quality Assurance
ViewRay, MRI-Guided RT
2 Thermo Fisher Way
OAKWOOD VILLAGE OH 44146

MAY 22 2012

Re: K111862
Trade/Device Name: The ViewRay™ System for Radiation Therapy
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 21, 2012
Received: March 23, 2012

Dear Ms. Brownlee:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K111862

Indications for Use

510(k) Number (if known): K111862

Device Name: The ViewRay™ System for Radiation Therapy

Indications for Use: The ViewRay 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.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K111862