RefleXion Medical, Inc
℅ Kathy O'Shaughnessy, PhD
V.P. Regulatory, Quality Assurance, Clinical
25841 Industrial Blvd, Suite 275
HAYWARD CA 94545

March 12, 2020.

Re: K190978
Trade/Device Name: RefleXion Medical Radiotherapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: February 13, 2020
Received: February 14, 2020

Dear Dr. O'Shaughnessy:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190978

Device Name
RefleXion Medical Radiotherapy System

Indications for Use *(Describe)*
The RefleXion Medical Radiotherapy System is indicated for treatment planning and precise delivery of image-guided radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery for tumors or other targeted tissues anywhere in the body when radiation treatment is indicated, while minimizing the delivery of radiation to vital healthy tissue. The megavoltage X-ray radiation is delivered in a rotational, modulated, image-guided format in accordance with the physician approved plan.

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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Premarket Notification [510(k)] Summary

RefleXion Medical Radiotherapy System RXM1000

SUBMITTER

RefleXion Medical, Inc.
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Hayward, CA 94545

Contact Name: Kathy O'Shaughnessy, PhD
Phone: (650) 239-9070 x1035
Fax: (650) 521-5916
Date of preparation: March 11, 2020

DEVICE

Name of Device: RefleXion Medical Radiotherapy System
Trade or Brand Name: RefleXion System One, RefleXion System RXM1000
Common/usual Name: Medical Linear Accelerator
Regulation Number: 21 CFR 892.5050
Classification Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code IYE (radiation therapy), MUJ (planning)

PREDICATE DEVICE

TomoTherapy Treatment System (K121934)

DEVICE DESCRIPTION

The RefleXion Medical Radiotherapy System (RMRS), a hybrid imaging-therapy system, is capable of delivering intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), stereotactic radiotherapy (SRT) and stereotactic radiosurgery (SRS) utilizing an on-board kilovoltage CT (kVCT) system for patient localization and field sizes based on jaws which are 40 cm wide, with slice width choices of 1.0 cm and 2.0 cm to optimize patient treatment. It is also equipped with a binary multileaf collimator (MLC) used to create intensity modulated radiation fields at a source-axis distance of 85 cm. It can achieve a nominal dose rate of 850 cGy/min.

The RMRS consists of the following clinical subsystems: 6 MV photon radiotherapy delivery, Kilovoltage (kV) X-ray CT imaging, MV X-ray detection, and treatment planning. The LINAC along with the fixed primary collimator, adjustable collimators, and multileaf collimator (MLC) mount in the therapy plane. The kVCT imaging plane is separate from the therapy plane and provides images used to localize the patient prior to treatment. Additionally, the system is designed architecturally to include PET imaging components for future product enhancements. Although the PET subsystem hardware is present in the system, its functionality is currently disabled.

INDICATIONS FOR USE/INTENDED USE STATEMENT

The RefleXion Medical Radiotherapy System is indicated for treatment planning and precise delivery of image-guided radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery for tumors or other targeted tissues anywhere in the body when radiation treatment is indicated, while minimizing the delivery of radiation to vital healthy tissue. The megavoltage X-ray radiation is delivered in a rotational, modulated, image-guided format in accordance with the physician approved plan.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The RefleXion Medical Radiotherapy System and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation and technological characteristics.

The treatment delivery components of the RefleXion and TomoTherapy devices are the same or equivalent with regards to energy, beam properties, materials and other physical properties.

Key differences between the subject device and the predicate device include the following:

- Faster rotation of the system at 60 RPM.
- Use of a new faster-speed binary MLC design.
- Addition of a kVCT subsystem for patient positioning.
- Addition of a method to correct for pitch and yaw set-up errors.

Device Characteristic	Predicate Device: TomoTherapy Treatment System	Subject Device: RefleXion Medical Radiotherapy System	Analysis
510(k) number	K121934	K190978	
Ring Gantry			
Bore Diameter	85 cm	85 cm	Same
Speed of Rotation Treatment Imaging	 1 to 5 RPM 6 RPM	 60 RPM 60 RPM	Substantially equivalent.
Photon Beam			
Beam energy	6 MV (single energy)	6 MV (single energy)	Same
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	1.0 cm x 40 cm 2.0 cm x 40 cm 3.0 cm x 40 cm (QA mode)	The field sizes for clinical use are substantially equivalent. Differences do not inhibit it's intended use.
Isocenter distance	85 cm	85 cm	Same
Nominal Dose Rate	850 cGy/min	850 cGy/min	Same
Collimation			
Primary Collimation	Tungsten block with rectangular, fixed aperture	Tungsten block with rectangular, fixed aperture	Same
Jaw placement	Jaws are placed after the MLC	Split jaw design – the lower jaws are placed after the MLC	Substantially equivalent. Subject device uses a split jaw design.

Device Characteristic	Predicate Device: TomoTherapy Treatment System	Subject Device: RefleXion Medical Radiotherapy System	Analysis
Jaw - movement	Static Mode Dynamic Mode	Static mode	Substantially equivalent. Subject device is static only.
Multileaf Collimator	0 to 400 mm wide by 5 to 20 mm long Binary (fully in or fully out); pneumatic 64 tungsten leaves (tongue and groove), 10cm thick	0 to 400 mm wide by 10 to 30 mm long Binary (fully in or fully out); spring-loaded pneumatic 64 tungsten leaves (tongue and groove), 11cm thick	Substantially equivalent. Minor differences are negligible.
Leaf Resolution at isocenter	0.625 cm in IEC-x direction at isocenter	0.625 cm in IEC-x direction at isocenter (leaf width is 0.614 cm)	Same
MLC Leaf transition time	<20 msec	<7 msec	Substantially equivalent. The subject device's MLC leaves move faster to accommodate faster gantry rotation.
Imaging – for patient positioning			
Energy	MVCT – 3.5 MV (nominal for positioning) Provided by the therapy beam (at lower energy)	kVCT – 120 kV Separate system located in a plane approx. 40 cm from therapy plane	Substantially equivalent.
Dose per image (typical)	0.5 – 3.0 cGy depending on resolution and body thickness	2.45 cGy (body), 5.13 cGy (head) ($CTDI_{vol,}$ nominal settings)	Similar; physician chooses at time of treatment planning
High contrast spatial resolution	3 lp/cm (typical)	4 lp/cm	Similar
Low contrast resolution	2% density for 2 cm object (typical)	Visibility of 5 mm object for 1% contrast	Subject device increases visibility of lower contrast/smaller objects
Treatment Planning			
Associated Treatment Delivery System	Determines treatment planning and dose distribution for the Tomotherapy System.	Determines treatment planning and dose distribution for the RefleXion System.	Same function for each system
Planning	6 MV External beam x-ray and inverse planning	6 MV External beam x-ray and inverse planning	Same
Image Series Used	Image series (CT)	Image series (CT)	Same
Treatment Delivery Software			
Delivery Modes Supported	IMRT, SRS, SRT, SBRT	IMRT, SRS, SRT, SBRT	Same
Patient Setup and Localization	Yes	Yes	Same
Patient Couch			
Biocompatible	Yes	Yes - Couch top is biocompatible	Same
Degrees of Freedom	Y, Z (software control) X (manual) Roll (adjust initial gantry angle) Pitch, yaw (rotate patient)	X, Y, Z, pitch, yaw (software control) Roll (adjust initial gantry angle)	The subject device adds software correction in the x, pitch and yaw axes.

PERFORMANCE DATA

Verification and validation testing have been conducted to demonstrate that the device performs as intended.

Bench testing included system and subsystem tests including:

- Performance tests to applicable standards (including electrical safety and electromagnetic compatibility).
- Safety/Interlock tests to ensure risk mitigations performed as specified.
- Dosimetric performance evaluation of the RefleXion system.
- Treatment Planning System Dose accuracy tests to evaluate the accuracy of the RefleXion treatment planning system.
- Geometric localization accuracy tests for the RefleXion system.
- Imaging performance testing.
- Validation testing including end-to-end tests, usability testing, and tests to ensure the system performance checks function as intended.

Results of bench testing showed conformance to applicable requirements and specifications. Specifications of key performance tests are provided below:

Performance Test	Specification
Coincidence of mechanical and radiation isocenter	≤ 1mm
kVCT imaging to MV treatment plane localization accuracy	≤ 1mm
kVCT geometric accuracy	≤ 1mm
Dosimetric accuracy	>90% of points passing 3%/3mm (for points greater than 10% maximum dose)
Dose rate output constancy	≤ 2%
Dose output linearity	± 2% ≥5MU ± 5% (2-4 MU)

Software verification and validation documentation was provided 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 software for this device was considered as a "major" level of concern.

The subject device conforms in whole or in part with the following standards: IEC60601-1, IEC60601-1-2, IE60601-1-3, IEC60601-1-6, IEC60601-2-1, IEC60601-2-44, IEC60601-2-68, IEC62304, IEC62366-1, IEC60976, IEC61217, IEC62083, IEC62274. For those recognized standards in which there are clauses that are not applicable, summary reports with justifications have been included in the submission.

No animal studies or clinical tests have been included with this pre-market submission.

CONCLUSION

The non-clinical data support the safety of the device and the verification and validation testing performed demonstrates that the RefleXion Medical Radiotherapy System performs as intended in the specified use conditions. RefleXion therefore considers the RefleXion Medical Radiotherapy System to be substantially equivalent to the predicate device.