Accuray Incorporated
% Keith Picker
Senior Regulatory Affairs Specialist
1240 Deming Way
MADISON WI 53717

November 23, 2018

Re: K182687
Trade/Device Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: September 25, 2018
Received: September 26, 2018

Dear Mr. Picker:

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 A. 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)*
K182687

Device Name
Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Indications for Use *(Describe)*
The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

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 8 510(k) Summary

Submitter

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Contact: Keith Picker
Date Prepared: September 25, 2018

Device Identification

Device Name:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Trade & Brand Names:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Common Name:	Radiation Therapy System
Regulation Number:	21 CFR 892.5050
Regulation Name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Product Code:	IYE

Predicate Device

Radixact Treatment Delivery System (K161146)

Device Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Technological Characteristics

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch.

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the predicate and subject devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is presented below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

Device Comparison Table: Radixact Treatment Delivery System with Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
System Description			
Intended Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
Indications for Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
System Configuration	Stand-alone radiation delivery system (does not include data management system or planning system)	Stand-alone radiation delivery system with kV imaging and motion tracking and compensation added (does not include data management system or planning system)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not raise different issues of safety or effectiveness.
Vault (Treatment Room)			
Minimum Room Dimensions (H*W*L)	274 x 462 x 602 cm	274.3 x 463 x 602 cm	Substantially equivalent. Minor differences are negligible.
Device Dimensions (gantry and couch) (H*W*L)	255 x 280 x 473 cm	255 x 280 x 470.5 cm	Substantially equivalent. Minor differences are negligible.
Device Mass (kg)	6580 kg	6580 kg plus 235 kg for kV subsystem components	The weight added due to the kV subsystem does not result in different questions of safety or effectiveness.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Line Voltage	380 – 480 V_{ac} 3-Phase	Same as predicate	Identical
Ambient Room Temperature	20 – 24 ºC	Same as predicate	Identical
Relative Humidity (non-condensing)	30 – 60 %	Same as predicate	Identical
Gantry Mechanical Features			
Bore Diameter	85 cm	Same as predicate	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Same as predicate	Identical
Direction of Rotation	Clockwise (as viewed from the foot of the couch)	Same as predicate	Identical
Rotational Speed (Treatment)	1 – 5 RPM	Same as predicate	Identical
Rotational Speed (Imaging)	10 RPM	Same as predicate	Identical
Couch Support in Bore	Provided	Same as predicate	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Same as predicate	Identical
Photon Beam			
Accelerator Type	Standing wave	Same as predicate	Identical
RF Source	Magnetron	Same as predicate	Identical
Nominal Energy	6 MV	Same as predicate	Identical
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Same as predicate	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Same as predicate	Identical
Dose Rate	850 cGy/min standard 1000 cGy/min optional	Same as predicate	Identical
Collimation			
Description	Primary collimation, jaws and multi-leaf	Primary collimation, jaws and multi-leaf collimator	Substantially equivalent. Jaws have

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
	collimator		a new dynamic behavior for motion managed plans. Jaws will continually be adjusted to repoint the beam at the moving target (in IEC-Y) while maintaining the same field size.
MVCT Imaging			
Source	Megavoltage Computed Tomography (MVCT)	Same as predicate	Identical
Field of View (MVCT)	39 cm diameter	Same as predicate	Identical
Dose per MVCT Image (typical)	0.5 – 3.0 cGy	Same as predicate	Identical
Slice Spacing (MVCT)	1, 2, 3, 4 and 6 mm reconstruction intervals	Same as predicate	Identical
Spatial Resolution (MVCT)	1.6 mm	Same as predicate	Identical
kV Imaging			
Source	Feature not present	50-150 kV Radiography Class I (60601-2-28) X-ray tube assembly	The kV Imaging subsystem provides two-dimensional low-dose radiographic images used for patient alignment and measurement of tumor motion during treatment delivery. The functionality is provided by hardware and driver software. A kV radiograph can be performed at any arbitrary angle. A stable calibration from
Field of View	Feature not present	20 cm x 20 cm	
Spatial Resolution (kV)	Feature not present	< 1 mm	
Approximate Dose per kV x-ray image (range)	Feature not present	0.08 – 0.20 mGy	
Small Focal Spot Size	Feature not present	0.6 mm x 0.6 mm	
Large Focus Spot Size	Feature not present	1.0 mm x 1.0 mm	
Current Range (mA)	Feature not present	5 - 500 mA	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			the kV Imaging coordinate system to the machine coordinate system is made during configuration of the TDS. The new kV imaging components meet applicable safety requirements in the IEC 60601 series.
Motion Management			
Tracking Algorithm	Not present	Radixact Motion Tracking	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature is based on the core tracking algorithm introduced in K120233, Synchrony Respiratory Tracking System.
Compensation Algorithm	Not present	Radixact Motion Compensation	The compensation algorithm uses the jaws and MLC to effectively repoint the beam to accommodate for motion in a method substantially equivalent to K120233, Synchrony Respiratory Tracking System. Does not result in different questions of safety or effectiveness.
Synchrony Camera	Not present	Radixact Synchrony Motion Tracking	Substantially equivalent. The Synchrony camera has

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			been in use for over ten years and was included most recently in K120233, Synchrony Respiratory Tracking System.
Laser System			
Stationary	Green lasers identify virtual and actual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Moveable (for patient positioning and registration)	Red lasers identify offset from virtual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Patient Couch			
Motion	Independent of each of the other axes	Independent of each of the other axes	Identical
Biocompatibility			
Couch Top	Carbon-fiber top	Carbon-fiber top	Identical
Synchrony Vest	Not Used	Same vest cleared under K120233, Synchrony Respiratory Tracking System	No new biocompatibility issues
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this subsystem.
UPS for Data Back-up	Provided	Provided	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			did not introduce changes to this design
Operator Station (Treatment Delivery Console)			
Description	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this architecture.
Machine Control Software			
Description	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Database			
Description	External database used for gathering operational data and storage of procedure data	External database used for gathering operational data and storage of procedure data	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design outside of accommodating for more data.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Safety Features			
Interlock Subsystems	Present	Present	Substantially equivalent. kV subsystem integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data integrity checking	Present	Present	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design.

Performance Data

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature was tested and shown to comply with the requirements of applicable FDA recognized consensus safety standards for radiation therapy equipment. Results of verification and validation testing confirm that the use of the Motion Tracking and Compensation Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests were required to establish substantial equivalence with the predicate device. The performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Further, these test results demonstrate that the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has substantially equivalent safety and performance characteristics in comparison to the predicate device.

Conclusion

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment

Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.