Accuray Incorporated
℅ Karla Fields
Senior Regulatory Affairs Specialist
1209 Deming Way
MADISON WI 53717

June 23, 2023

Re: K223159
Trade/Device Name: 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: May 23, 2023
Received: May 24, 2023

Dear Karla Fields:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.06.23 07:54:07 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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)*
K223159

Device Name
The Radixact Treatment Delivery System

Indications for Use *(Describe)*
The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic body radiotherapy (SBRT), or stereotactic radiosurgery (SRS) to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner. 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. The Radixact Treatment Delivery System integrates Surface Guided Radiation Therapy (SGRT) for patient setup, patient position and motion monitoring, and breath-hold gating.

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

AS REQUIRED BY 21 CFR 807.92

510(k) Number:	K223159
Product Name:	Radixact Treatment Delivery System
Date Prepared:	June 22, 2023
Submitter:	Accuray Incorporated 1209 Deming Way Madison, Wisconsin 53717
Primary Contact Person:	Karla Fields (608) 824-2990 kfields@accuray.com
Secondary Contact Person:	Michael Preto (608) 405-9427 mpreto@accuray.com
Common or Usual Name	Medical Linear Accelerator
Regulation:	21 CFR 892.5050
Classification Name:	892.5050 Medical charged-particle radiation therapy system
Regulatory Class:	II
Product Code:	IYE
Primary Predicate Device:	Radixact Treatment Delivery System, K202412
Reference Device:	Radixact Treatment Delivery System, K182687

Device Description
The primary predicate Radixact Treatment Delivery System was last cleared on K202412.

The predicate and modified Radixact Treatment Delivery Systems are radiation therapy delivery systems, that provide megavoltage CT imaging capabilities coupled with x-ray radiation delivery. The system achieves delivery using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three-dimensional conformal) radiation therapy treatment techniques utilizing image-guided (IGRT) or non-image-guided workflows, to tumors or other targeted tissues anywhere in the body, in accordance with the physician-approved plan.

The additional feature update: VitalHold incorporates an external optical monitoring system (EMS), which is integrated with the Radixact system to enable Surface Guided Radiotherapy (SGRT) for patient setup, patient position and motion monitoring, and breath-hold gating.

Neither the predicate Radixact Treatment Delivery System nor the modified Radixact Treatment Delivery System diagnose disease or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

Intended Use
The Radixact Treatment Delivery System is intended for the delivery of radiation therapy, stereotactic body radiotherapy (SBRT), or stereotactic radiosurgery (SRS) to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner. 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.

Indication for Use
The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic body radiotherapy (SBRT), or stereotactic radiosurgery (SRS) to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner. 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. The Radixact Treatment Delivery System integrates Surface Guided Radiotherapy (SGRT) for patient setup, patient position and motion monitoring, and breath-hold gating.

Significant Differences
The new functionality added to the modified Radixact Treatment Delivery System provides an enhanced user experience. The primary focus of the additional updates within this submission for the modified Radixact Treatment Delivery System are:

1) To provide integration of a Surface-Guided Radiotherapy (SGRT) system, through an optional interface VitalHold utilized for breath-hold gating capabilities

2) Switching of the intended use and indications for use statements, to their appropriate descriptors (with the feature update included in this submission)

The primary function of VitalHold encompasses a licensable feature that integrates a Surface Guided Radiotherapy (SGRT) system through the Accuray Connect – Surface Imaging interface. VitalHold can be used for real-time optical patient setup and monitoring and to perform breath-hold gating techniques like deep inspirational breath-hold (DIBH) and allows an external system to gate the MV beam during treatment delivery for the purpose of breath-hold gating and/or monitoring of patient positioning during treatment. Note that breath-hold gating can be used to do DIBH, but DIBH is just one of several clinical techniques that can be delivered by using the breath-hold gating feature. This feature also includes the enhanced ability to turn the MV beam on in under one second.

Summary of Technological Characteristics

The modified Radixact Treatment Delivery System has imaging and treatment capabilities similar to those of the predicate Radixact Treatment Delivery System. It also incorporates a functionally equivalent CT-style gantry and patient couch.

Additionally, the predicate and subject devices have substantially equivalent performance specifications, technological characteristics, and incorporate ClearRT helical kVCT imaging (complementing the feature addition in this submission). Further, the predicate and modified Radixact Treatment Delivery System are comprised of the same fundamental scientific principles and have substantially equivalent principles of operation.

The main difference between the predicate and the subject device is the integration of VitalHold the licensable feature discussed. The Intended Use and Indications for Use have been modified (switching them to their appropriate descriptors) with the Intended Use Statement to be more general and the Indications for Use to be more specific. The feature addition supported by the results of the verification and validation activities, the additional acronyms and specificity added to the Indications for Use are considered minor, as outlined in the table below. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

Device Characteristic	Predicate Device	Subject Device	Comparison
Intended Use	**ClearRT Helical kVCT for the Radixact Treatment Delivery System (K202412)**	**Radixact Treatment Delivery System**	**Analysis**
Intended Use	The kVCT Imaging 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.	The Radixact Treatment Delivery System is intended for the delivery of radiation therapy, stereotactic body radiotherapy (SBRT) or stereotactic radiosurgery (SRS) to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner. 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.	Addition of acronyms (features), switching Intended Use Statement to be more general.

Device Characteristic	Predicate Device	Subject Device	Comparison
Indications for Use	**ClearRT Helical kVCT for the Radixact Treatment Delivery System (K202412)**	**Radixact Treatment Delivery System**	**Analysis**
Indications for Use	The kVCT Imaging 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 Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic body radiotherapy (SBRT) or stereotactic radiosurgery (SRS) to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner. 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. The Radixact Treatment Delivery System integrates Surface Guided Radiation Therapy (SGRT) for patient setup, patient position and motion monitoring, and breath hold gating.	Addition of acronyms (features), switching Indications for Use Statement to be more specific. Addition of SGRT. The SGRT statement is supported by the VitalHold feature updates: incorporating an external optical monitoring system (EMS), integrated with the Radixact system for patient setup, patient position along with motion monitoring, and breath-hold gating. The optional feature update does not raise additional questions of safety and effectiveness supported by the results of the verification and validation activities, the additional acronyms and specificity. Adding to the Indications for Use is considered minor.

Device Characteristic	Predicate Device	Subject Device	Comparison
Classification Regulation, Product Code & System Configuration	**ClearRT Helical kVCT for the Radixact Treatment Delivery System (K202412)**	**Radixact Treatment Delivery System**	**Analysis**
Classification, Regulation, Product Code	§892.5050 Medical charged-particle radiation therapy system, class II, IYE	§892.5050 Medical charged-particle radiation therapy system, class II, IYE	Identical
System Configuration	Stand-alone radiation delivery system with kV imaging added (does not include data management system or planning system)	Stand-alone radiation delivery system with ClearRT & kV imaging (does not include data management system or planning system) with gated motion management.	Administrative updates. kV Radiographs and Motion Tracking introduced in K182687. kVCT introduced in K202412. Updates to brand names. Inclusion of Gated Motion Management.
Radiation Source			
Nominal Beam Energy	6 MV	6 MV	Identical
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 2.5 cm x 40 cm 5.0 cm x 40 cm	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Identical
Isocenter Distance	850 mm	850 mm	Identical
Dose Rate (standard)	850 cGy/min	850 cGy/min	Identical
Dose Rate (optional)	1000 cGy/min	1000 cGy/min	Identical
Collimation			
Primary Collimation Method	Rectangular, fixed tungsten aperture	Rectangular, fixed tungsten aperture	Identical
Collimation Size (MLC)	40 cm total width	40 cm total width	Identical
Collimation Transition Time (MLC)	< 30 ms (MLC)	< 30 ms (MLC)	Identical

Device Characteristic	Predicate Device	Subject Device	Comparison
MVCT Imaging			
Energy/Type (source)	Megavoltage Computed Tomography	Megavoltage Computed Tomography	Identical
Field of View Size	39 cm diameter	39 cm diameter	Identical
Contrast Resolution (FBP-Filtered Back Projection)	3% contrast for 30 mm object or better	3% contrast for 30 mm object or better	Identical
Contrast Resolution (ITR-Iterative Reconstruction)	2% contrast for 20 mm object or better	2% contrast for 20 mm object or better	Identical
Spatial Resolution	1.6 mm (at 3.2 mm intervals)	1.6 mm (at 3.2 mm intervals)	Identical
Dose	1.1 – 3.4 cGy (CTDIvol, Head) 0.8 – 2.5 cGy (CTDIvol, Body)	1.1 – 3.4 cGy (CTDIvol, Head) 0.8 – 2.5 cGy (CTDIvol, Body)	Identical
Spatial Integrity	1 mm	1 mm	Identical, same capability as original system
kVCT Imaging	**ClearRT Helical kVCT for the Radixact Treatment Delivery System (K202412)**	**Radixact Treatment Delivery System**	**Analysis**
Source	40 – 150 kV Radiography Class I (60601-2-28) X-ray tube assembly	40 – 150 kV Radiography Class I (60601-2-28) X-ray tube assembly	Identical
Field of View (FOV) options	25 - 50 cm	27 - 50 cm	Small adjustment to lower end of the range. Minor differences are negligible and do not result in different questions of safety or effectiveness.
Scan Length	Up to 135 cm continuous	Up to 135 cm continuous	Identical.
Imaging Dose	0.6 - 4.3 (CTDIvol, Head) 0.4 - 2.3 (CTDIvol, Body)	0.17- 2.6 (CTDIvol, Head) 0.21 - 3.1 (CTDIvol, Body)	No changes made, slight differences due to fine-tuning of protocols. The latest measurements for CTDIvol, head were measured for Head protocols only. CTDIvol, body was measured for Thorax, Pelvis, and Whole Body.
Slice Spacing	1.2, 1.8, 3.6 mm	1.2, 1.8, 3.6 mm	Identical.
Spatial Resolution	1.0 mm (at 2.0 mm intervals)	1.0 mm (at 2.0 mm intervals)	Identical.
Image Size	512 x 512 pixels	512 x 512 pixels	Identical.

Device Characteristic	Predicate Device	Subject Device	Comparison
Spatial Integrity	0.5 mm	0.5 mm	Identical.
Low Contrast Resolution	1% contrast for 10 mm object (20 cm phantom) 2% contrast for 15 mm object (30 cm phantom)	1% contrast for 10 mm object (20 cm phantom) 2% contrast for 15 mm object (30 cm phantom)	Identical.
Physical Geometry			
Bore size (diameter)	85 cm	85 cm	Identical
Minimum Room Dimensions (H*W*L)	274.3 x 463 x 602 cm	Approximately 270 x 462 x 602 cm	Substantially equivalent. Minor differences are negligible.
Patient Couch – Degrees of Freedom	Independent of each of the other axes X: +/- 2.5 cm Y: 145 cm Z: at least 2 cm below isocenter	Independent of each of the other axes X: +/- 2.5 cm Y: 145 cm Z: at least 2 cm below isocenter	Substantially equivalent. Does not result in different questions of safety or effectiveness.
Patient Surface – Biocompatibility (Couch Top)	Carbon-fiber top	Carbon-fiber top and Synchrony vest/fiber optic assembly	Substantially equivalent. ISO 10993-1 compliant. First introduced to Radixact on K182687. Does not result in different questions of safety or effectiveness.

Performance Data

The modified Radixact Treatment Delivery System was verified and validated according to the FDA Quality System Regulation (21 CFR §820) and other FDA recognized consensus standards listed below. 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 verification and validation testing were completed and documented in conformance with guidance document *Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005).

Standards

The performance of the modified Radixact Treatment Delivery System has been evaluated and tested for electrical safety and EMC compliance by the independent NRTL test house Intertek Testing Services to the following standards*:

FDA Rec #	Standard Designation	Short Title
19-4	ANSI AAMI ES60601-1:2005/ (R) 2012 and A1:2012, C1:2009/(R)2012 and 2:2010/(R)2012	General requirements for basic safety and essential performance
19-36	IEC 60601-1-2 Edition 4.1 2020-09	Electromagnetic Compatibility - Requirements and Tests
12-269	IEC 60601-1-3 Ed. 2.1 2013-04	Radiation Protection in Diagnostic X-ray Equipment.
12-285	IEC 60601-2-1 Ed. 3.1 2014-07	Electron Accelerators in the Range 1 MeV to 50 MeV
12-319	IEC 60601-2-68 Ed. 1.0 2014-09	X-ray-based Image-Guided Radiotherapy Equipment for use with Electron Accelerators, Light Ion Beam Therapy Equipment and Radionuclide Beam Therapy Equipment
12-307	AAMI RT2:2017	Radiation therapy readiness check
5-89	IEC 60601-1-6 Edition 3.1 2013-10	Usability

Regulatory References

In accordance with the regulatory references containing product requirements, the modified Radixact Treatment Delivery System conforms to the following:

- 21 CFR §820 – Quality System Regulation
- ISO 13485: 2016 Medical devices - Quality management systems
- ISO 14971: 2019 Medical devices - Applications of risk management to medical devices

Non-Clinical Data

Breath-hold gating is enabled by the integration of Radixact with a Surface Guided Radiotherapy (SGRT) system. The use of an SGRT system with Radixact also provides the clinician with the ability to perform optical setup, and patient surface monitoring during treatment. We described the new features that are added on Radixact and their benefits in treatment of cases are described further in the executive summaries. We also showed the advantages these features have compared to using traditional methods. We discussed the design concept and how the implementation supports the automatic use of Radixact with an SGRT device, in other words, enables this new feature.

Key system performance attributes were evaluated:
1. Track a moving surrogate
2. Deliver treatment beam to the surrogate
3. Pause the treatment beam when the surrogate has moved out of a defined threshold, i.e., gating window
4. Inform the user to resume the treatment beam when the surrogate moves within the defined threshold

This testing outlined above and included in this submittal has been performed to ensure that we deliver a safe and effective design, hence a safe product. Data within this submission and specifically, the executive summaries, include data, discussion, and results. The Verification results show that the design goals and objectives had been met. These summaries along with raw data within our submission support the feature addition and claim that the modified Radixact Treatment Delivery System is as safe and effective as the predicate device. Therefore, the modified Radixact Treatment Delivery System is substantially equivalent to the predicate device.

Clinical Testing

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

Conclusion

The modified Radixact Treatment Delivery System is substantially equivalent to the predicate Radixact Treatment Delivery System. The intended use and indications for use of the modified Radixact Treatment Delivery System include feature acronyms included with this submission, switching of the Intended Use Statement to be more general, and the Indications for Use Statement to be more specific. A detailed comparison of the similarities and differences between the predicate and modified Radixact Treatment Delivery Systems is provided in this submission. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

The final results of verification and validation, as well as conformance to relevant safety standards, demonstrate that the modified Radixact Treatment Delivery System meets the safety and performance criteria and is substantially equivalent with reference to safety and effectiveness to the predicate Radixact Treatment Delivery System.