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

December 18, 2020

Re: K202412
Trade/Device Name: kVCT Imaging 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: November 24, 2020
Received: November 25, 2020

Dear Keith 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/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)*
K202412

Device Name
kVCT Imaging Feature for the Radixact Treatment Delivery System

Indications for Use *(Describe)*
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.

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

K202412

Submitter

Accuray Incorporated
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Madison, WI 53717
Phone: 608-824-3069
Fax: 608-824-2996

Contact: Keith Picker
Date Prepared: November 24, 2020

Device Identification

Device Name:	kVCT Imaging Feature for the Radixact Treatment Delivery System
Trade & Brand Names:	ClearRT Helical kVCT 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)

Reference Device:

Motion Tracking And Compensation Feature For The Radixact Treatment Delivery System (K182687)

Device Description

The kVCT Imaging Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The primary functions of the kVCT Imaging Feature are: 1) acquisition of kV x-ray images according to input protocols in concert with other subsystems, 2) correcting 2D images and 3) returning reconstructed 3D images.

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 kVCT Imaging Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

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.

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 intended use and indications for use statements for the kVCT Imaging 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 as kVCT Imaging is a type of Image Guided Radiotherapy (IGRT).

Technological Characteristics

The Radixact Treatment Delivery System with the use of the kVCT Imaging 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 kVCT Imaging 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 kVCT Imaging 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 kVCT Imaging 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 kVCT Imaging Feature and the predicate device is presented below in Table 5.5.1. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

A table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the kVCT Imaging Feature and the reference device (K182687) is provided in Table 5.5.2 below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness. The kV Imaging subsystem provides three-dimensional CT images with equivalent or better performance than the predicate device (MVCT). The kVCT energy range offer improved intrinsic tissue contrast and image quality characteristics compared to that of MVCT imaging.

Table 5.5.1 Device Comparison Table: Radixact Treatment Delivery System with kVCT Imaging Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
System Description			
Intended Use	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 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.	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
Indications for Use	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 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.	Identical
Classification	§892.5050 Medical charged-particle radiation therapy system, class II	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 added (does not include data management system or planning system)	Substantially equivalent. The introduction of the kVCT imaging feature does not raise different issues of safety or effectiveness. The risk acceptability determination was not impacted by the modified design.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
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 + 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	7000 kg (approximate)	Substantially equivalent. The added mass due to the kVCT imaging subsystem does not result in different questions of safety or effectiveness.
Line Voltage	380 – 480 Vac 3-Phase	380 – 480 Vac 3-Phase	Identical
Ambient Room Temperature	20 – 24 ºC	20 – 24 ºC	Identical
Relative Humidity (non-condensing)	30 – 60 %	30 – 60 %	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
Gantry Mechanical Features			
Bore Diameter	85 cm	85 cm	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Continuous rotation around Y- axis (axes per IEC 61217)	Identical
Direction of Rotation	Clockwise	Clockwise	Identical
Rotational Speed (Treatment)	1 – 5 RPM	1 – 5.08 RPM	Substantially equivalent. Minor differences are negligible and do not result in different questions of safety or effectiveness.
Rotational Speed (Imaging)	10 RPM	Up to 10 RPM	Substantially equivalent. Rotational speed is unchanged for MVCT imaging. Slower speeds are used for some kVCT imaging applications.
Couch Support in Bore	Provided	Provided	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Helical, Direct	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
Photon Beam			
Accelerator Type	Standing wave	Standing wave	Identical
RF Source	Magnetron	Magnetron	Identical
Nominal 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
Dose Rate	850 cGy/min standard 1000 cGy/min optional	850 cGy/min standard 1000 cGy/min optional	Identical
MV Beam Collimation			
Description	Primary collimation, jaws and multi-leaf collimator (MLC)	Primary collimation, jaws and multi-leaf collimator (MLC)	Substantially equivalent. kVCT does not change the behavior of the jaws.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
MVCT Imaging			
Source	Megavoltage Computed Tomography	Megavoltage Computed Tomography	Identical
Field of View (FOV)	39 cm diameter	39 cm diameter	Identical
Scan Length [Specification not detailed in K161146]	135 cm	135 cm	Identical
Imaging Dose	0.5 – 3.0 cGy (imaging dose near center of Tomo-Phantom)	1.1 – 3.4 cGy ($CTDI_{vol}$, Head) 0.8 – 2.5 cGy ($CTDI_{vol}$, Body)	Identical. Differences shown are due to additional detail provided and dose characterized in $CTDI_{vol}$
Slice Spacing	1, 2, 3, 4 and 6 mm reconstruction Intervals	1, 2, 3, 4 and 6 mm reconstruction Intervals	Identical
Spatial Resolution	1.6 mm	1.6 mm (at 3.2 mm intervals)	Substantially equivalent
Image Size [Specification not detailed in K161146]	512 x 512 pixels	512 x 512 pixels	Identical
Image Uniformity [Specification not detailed in K161146]	Within 25 HU	Within 25 HU	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
Image Noise [Specification not detailed in K161146]	Less than 43 HU	Less than 43 HU	Substantially equivalent
Contrast Resolution [Specification not detailed in K161146]	3% contrast for 30 mm object	3% contrast for 30 mm object or better	Substantially equivalent
Acquisition Trajectory [Specification not detailed in K161146]	Helical	Helical	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
kVCT Imaging			
Imaging Dose	Feature not present	0.6 - 4.3 ($CTDI_{vol}$, Head) 0.4 - 2.3 ($CTDI_{vol}$, Body)	Substantially equivalent. The kV Imaging subsystem provides three-dimensional CT images with equivalent or better performance than the predicate device (MVCT). The kVCT energy range offer improved intrinsic tissue contrast and image quality characteristics compared to that of MVCT imaging.
Acquisition Trajectory	Feature not present	Helical	
Slice Spacing	Feature not present	1.2, 1.8, 3.6 mm	
Spatial Resolution	Feature not present	1.0 mm (at 2.0 mm intervals)	
Image Size	Feature not present	512 x 512 pixels	
Scan Length	Feature not present	Up to 135 cm	
Field of View (FOV)	Feature not present	25 - 50 cm	
Image Uniformity	Feature not present	Within 15 HU (Head) Within 25 HU (Body)	
Image Noise	Feature not present	Less than 10 HU (Head) Less than 20 HU (Body)	
Contrast Resolution	Feature not present	1% contrast for 10 mm object (Head) 2% contrast for 15 mm object (Body)	
Image Display	Feature not present	Simultaneous acquisition and reconstruction; real time display	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
Laser System			
Stationary	Green lasers, identify virtual and actual isocenter	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, offset from virtual isocenter	Red lasers, offset from virtual isocenter	
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
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. This feature is still present.
UPS for Data Back-up	Provided	Provided	Substantially equivalent. This feature is still present.
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 modified device does not change this architecture.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
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, except for the following: Controls were added for the dynamic kV Collimator and kV Panel Actuator, and kV triggering
Database			
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The kVCT imaging 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 kVCT imaging 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 kVCT Imaging Feature	Analysis
Safety Features			
Interlock Subsystems	Interlock Subsystems	Present	Substantially equivalent. The kV subsystem is integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data Integrity Checking	Data Integrity Checking	Present	Substantially equivalent. This feature is still present in the modified device.

Table 5.5.2: Device Comparison Table: Radixact Treatment Delivery System with kVCT Imaging Feature and the Reference Device

Device Characteristic	Reference Device Motion Tracking and Compensation for Radixact (K182687)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
MV Beam Collimation	Primary collimation, jaws and multi-leaf collimator (MLC)	Primary collimation, jaws and multi-leaf collimator (MLC)	kVCT does not change the behavior of the jaws. Identical to the dynamic behavior introduced in K182687.
Machine Control Software	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, except for the following: Controls were added for the dynamic kV Collimator and kV Panel Actuator, and kV triggering was modified. These controls are similar in nature to those introduced in K182687.

Device Characteristic	Reference Device Motion Tracking and Compensation for Radixact (K182687)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
kV Imaging Beam			
Source	50 – 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	Substantially equivalent. The X-ray generation assembly (including the tube) has been updated to handle the increased demands of kVCT imaging over the solely 2-D radiograph imaging available in the predicate.
Focal Spot Size	0.6 mm x 0.6 mm (small spot) 1.0 mm x 1.0 mm (large spot)	0.6 mm x 0.6 mm (small spot) 1.2 mm x 1.2 mm (large spot)	
Anode Heat Capacity	600 kHU	1500 kHU	
Tube Heat Management [Specification not detailed in K182687]	Passive	Active oil cooled, 2.4 kW	
Generator specifications [Specification not detailed in K182687]	400/480 V, 45 kW	400/480 V, 80 kW	
Source to axis distance [Specification not detailed in K182687]	575 mm	1040 mm	Substantially equivalent. The combination of source to axis distance, source to detector distance and pixel pitch have been modified in the subject device with no material impact.
Source to detector distance [Specification not detailed in K182687]	1130 mm	1560 mm	

Device Characteristic	Reference Device Motion Tracking and Compensation for Radixact (K182687)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
kV Beam Filtering & Collimation			
kV Collimation (description) [Specification not detailed in K182687]	Static collimation	Dynamic IEC-Xb collimating blades, Dynamic IEC-Yb collimating blades	Substantially equivalent. This impacts kV radiographs, since the modified device now limits the imaging beam to the active area of the kV detector using the collimator blades, as opposed to the static collimation used in the predicate.
kV Spectral Filtering (description) [Specification not detailed in K182687]	0.5 mm copper	Dynamically selectable filter of 0.2 mm, 0.3, or 0.5 mm copper, or open air	Substantially equivalent. There is no impact relative to the reference device, since the modified device continues to use the 0.5 mm copper filter available

Device Characteristic	Reference Device Motion Tracking and Compensation for Radixact (K182687)	Subject Device Radixact Treatment Delivery System with kVCT Imaging Feature	Analysis
kV Detector			
Active Area [Specification not detailed in K182687]	410 mm x 410 mm 1024x1024 pixels, 0.4 mm pitch	432 mm x 432 mm 2880x2880 pixels, 0.15 mm pitch	Substantially equivalent. The subject device provides the same or better active area with the same or better pixel resolution as compared to the reference device.
Detector Configuration	Flat panel CsI: Tl Thallium activated Cesium Iodide	Flat panel CsI: Tl Thallium activated Cesium Iodide	Substantially equivalent. The materials have not changed.
Actuation	Feature not present	-225 to +25 mm along the IEC-Xr axis (axes per IEC 61217)	Substantially equivalent. The modified device can dynamically collimate the beam to the detector position

Performance Data

The Radixact Treatment Delivery System with the use of the kVCT Imaging 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 kVCT Imaging Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests are being submitted to establish substantial equivalence with the predicate device. The performance data demonstrate that the kVCT Imaging Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the kVCT Imaging 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 kVCT Imaging 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 kVCT Imaging Feature is substantially equivalent to the predicate device. The intended use and indications for use of the kVCT Imaging 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 kVCT Imaging 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 kVCT Imaging Feature in comparison to the predicate device. Further, the performance data demonstrate that the kVCT Imaging Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the kVCT Imaging 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 kVCT Imaging Feature is substantially equivalent to the predicate device.