



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Accuray Incorporated  
% Mr. Keith Picker  
Regulatory Affairs Specialist  
1209 Deming Way  
MADISON WI 53717

June 24, 2016

Re: K161146  
Trade/Device Name: Radixact Treatment Delivery System  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: April 22, 2016  
Received: April 22, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161146

Device Name

Radixact Treatment Delivery System

Indications for Use (Describe)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Section 8      510(k) Summary

### Submitter

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Contact:                      Keith Picker  
Date Prepared:              April 25, 2016

### Device Identification

Device Name:	Radixact Treatment Delivery System
Trade & Brand Names:	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

TomoTherapy Treatment System (K121934)

### Device Description

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.

The Radixact Treatment Delivery System is an updated design of the radiation delivery elements of the predicate TomoTherapy Treatment System (last cleared on K121934). The Radixact Treatment Delivery System delivers radiation therapy treatment plans generated on planning systems such as Accuray's Precision™ Treatment Planning System and stored on Accuray's iDMS™ Integrated Data Management System devices. The planning and data management devices are not addressed in this 510(k).

The Radixact Treatment Delivery System is a prescription device that delivers radiation in accordance with a physician approved plan. As with the TomoTherapy Treatment System, the Radixact Treatment Delivery System does not diagnose disease, recommend

treatment regimens or quantify treatment effectiveness. Accordingly, it is not intended for diagnostic use.

### **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.

### **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.

While the indications for use of the Radixact Treatment Delivery System are stated slightly differently from those of the predicate, the differences are not critical to the intended use of the devices nor do they affect the safety and/or effectiveness of the new device as compared to the predicate device. Both devices provide the same types of radiation therapy.

### **Technological Characteristics**

The Radixact Treatment Delivery System has imaging and treatment capabilities equivalent to those of the predicate TomoTherapy Treatment System. It also has a similar functionally-equivalent CT style gantry and patient couch. Further, the clinical workflow is the same as that of the predicate TomoTherapy Treatment System.

The Radixact Treatment Delivery System and the predicate device employ the same fundamental scientific principles, and have substantially equivalent technological characteristics and principles of operation. The main difference between the predicate TomoTherapy Treatment System and the Radixact Treatment Delivery System is that the predicate includes integral treatment planning and data management subsystems, whereas the Radixact Treatment Delivery System is strictly a radiation treatment delivery device.

Where there are technological differences between the Radixact Treatment Delivery System and the predicate device, those differences do not raise different questions of safety or effectiveness.

A table comparing the predicate cleared on K121934 and the Radixact Treatment Delivery System is presented below:

<b>General Characteristics</b>	<b><u>Predicate Device</u> TomoTherapy Treatment System (K121934)</b>	<b><u>Subject Device</u> Radixact Treatment Delivery System</b>
<b>System Configuration</b>	Radiation delivery system integrated with data management system and planning system	Stand alone radiation delivery system (does not include data management system or planning system)
<b>Vault</b>  Min. Room Dimensions Height* Width* Length*  Device Dimensions (gantry and couch) Height* Width* Length* Weight  Environment Line Voltage Ambient Room Temperature Relative Humidity	  270 cm 462 cm 596 cm  252 cm 280 cm 466 cm 4,943 kg  380-480V, 3-Phase  68-75 °F (20-24 °C) 30%-60%, non-condensing	  274 cm** 462 cm** 602 cm**  255 cm** 280 cm** 473 cm** 6580 kg**  Identical to predicate  Identical to predicate Identical to predicate

<b>Gantry Mechanical Features</b>		
Degrees of Rotation	Continuous rotation around Y-axis (axes per IEC 61217)	Identical to predicate
Direction of Rotation	Clockwise	Identical to predicate
Bore Size	85 cm diameter	Identical to predicate
Speed of Rotation Treatment Imaging	1 to 5 RPM 6 RPM	Identical to predicate 10 RPM
Couch Support in Bore	Not provided	Provided
<b>Radiation Delivery Modes</b>	Helical	Identical to predicate
	Direct	Identical to predicate
<b>Photon Beam</b>		
Accelerator Type	Standing wave	Identical to predicate
RF Source	Magnetron	Identical to predicate
Nominal Energy	6 MV	Identical to predicate
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Identical to predicate Identical to predicate Identical to predicate
Dynamic Field Size	1.0 - 2.5 cm x 40 cm 1.0 - 5.0 cm x 40 cm	Identical to predicate Identical to predicate
Dose Rate	850 cGy/min	850 cGy/min or 1000 cGy/min options
<b>Collimation</b>	Primary collimation, jaws and multi-leaf collimator (MLC)	Identical to predicate

<b>General Characteristics</b>	<b><u>Predicate Device</u> TomoTherapy Treatment System (K121934)</b>	<b><u>Subject Device</u> Radixact Treatment Delivery System</b>
<b>Imaging</b>  Field of View  Dose per MVCT image (typical)  Slice spacing  Spatial Resolution	39 cm diameter  0.5 - 3.0 cGy  1, 2, 3, 4 and 6 mm reconstruction intervals  1.6 mm spatial resolution	Identical to predicate  Identical to predicate  Identical to predicate  Identical to predicate
<b>Laser System</b>  Stationary  Moveable (for patient positioning and registration)	Green lasers, identify virtual and actual isocenter  Red lasers, offset from virtual isocenter	Identical to predicate  Identical to predicate
<b>Patient Couch</b>  Biocompatibility  Motion X-axis Y-axis  Z-axis	Carbon-fiber top  Independent of other axes Coupled with Z-axis (via couch Cobra motion) Coupled with Y-axis (via couch Cobra motion)	Equivalent to predicate  Identical to predicate Independent of other axes  Independent of other axes
<b>Power Distribution</b>  Isolation  UPS for Data Back-up	Transformer  Provided	Equivalent to predicate  Equivalent to predicate

<b>General Characteristics</b>	<b><u>Predicate Device</u> TomoTherapy Treatment System (K121934)</b>	<b><u>Subject Device</u> Radixact Treatment Delivery System</b>
<b>Operator Station</b>	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Functionally equivalent to predicate
<b>Machine Control Software</b>  Data Interfaces Operator Station	Controls radiation delivery and positioning systems (referred to as the RDS – Radiation Delivery System)  Provides measurements and status during operation	Functionally equivalent to predicate (referred to as the ECS – Embedded Controls Subsystem)  Functionally equivalent to predicate
<b>Database</b>	Integrated database used for gathering operational data and storage of procedure data	Works with functionally-equivalent external database
<b>Safety Features</b>	Interlock Subsystems  Data integrity checking	Functionally equivalent to predicate  Functionally equivalent to predicate

\* Dimensions are rounded to the nearest centimeter.

\*\* Information Source: Radixact Site Planning Guide T-SPG-01000, Rev A.

### **Performance Data**

The Radixact Treatment Delivery System was tested and shown to be in compliance with the requirements of applicable recognized consensus safety standards for medical devices. Results of verification and validation testing confirm that the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users. No clinical tests were required to establish substantial equivalence. The performance data demonstrate that the Radixact Treatment Delivery System is as safe and effective, and performs as well as the predicate device.

**Conclusion**

The Radixact Treatment Delivery System is substantially equivalent to the predicate device. The intended use, major technological characteristics and the principles of operation of the Radixact Treatment Delivery System 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 in comparison to the predicate device. Further, performance data demonstrate that the Radixact Treatment Delivery System is as safe and effective, and performs as well as the predicate device. Accordingly, the Radixact Treatment Delivery System is substantially equivalent to the predicate device.