DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 25, 2017

Accuray Incorporated
% Mr. Keith Picker
Senior Regulatory Affairs Specialist
1240 Deming Way
Madison, WI 53717

Re: K171837
Trade/Device Name: TomoTherapy Treatment Delivery System with iDMS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 19, 2017
Received: June 20, 2017

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. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171837

Device Name
TomoTherapy Treatment Delivery System with iDMS

Indications for Use *(Describe)*
The TomoTherapy Treatment Delivery System with iDMS 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

Accuray Incorporated
1209 Deming Way
Madison, WI 53717-1954
Phone: 608-824-2800
Fax: 608-824-2996

Contact: Keith Picker
Date Prepared: June 19, 2017

Device Identification

Device Name:	TomoTherapy Treatment Delivery System with iDMS
Trade & Brand Names:	TomoTherapy Treatment Delivery System with iDMS
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 TomoTherapy Treatment Delivery System with iDMS 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 TomoTherapy Treatment Delivery System with iDMS is a modified version of the predicate TomoTherapy Treatment System (last cleared on K121934). The TomoTherapy Treatment Delivery System with iDMS is the same as the predicate device minus the Data Management System and Treatment Planning Station, but substituting the Treatment Delivery Console (TDC) from the Radixact Treatment Delivery System (last cleared on K161146) in place of the predicate Operator Station. The TomoTherapy Treatment Delivery System with iDMS is designed to deliver radiation therapy treatment plans generated on planning systems such as the Accuray Precision™ Treatment Planning System (last cleared on K171086) and stored on data management systems such as the Accuray iDMS™ Integrated Data Management System (last cleared on K161144).

The TomoTherapy Treatment Delivery System with iDMS is a prescription device that delivers radiation in accordance with a physician approved plan. As with the predicate, the TomoTherapy Treatment Delivery System with iDMS does not diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, it is not intended for diagnostic use.

Intended Use

The TomoTherapy Treatment Delivery System with iDMS 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 TomoTherapy Treatment Delivery System with iDMS 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 TomoTherapy Treatment Delivery System with iDMS 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. In fact, the intended use and indications for use statements for the TomoTherapy Treatment Delivery System with iDMS (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the substitution of the device name.

Technological Characteristics

The TomoTherapy Treatment Delivery System with iDMS has imaging and treatment capabilities equivalent to those of the predicate TomoTherapy Treatment System. In fact, the TomoTherapy Treatment Delivery System with iDMS uses the same CT style gantry, patient couch and power distribution unit (PDU) as the predicate. Further, the clinical workflow is the same as that of the predicate TomoTherapy Treatment System.

The TomoTherapy Treatment Delivery System with iDMS and the predicate device employ the same fundamental scientific principles, and have substantially equivalent intended uses, principles of operation, performance specifications and technological characteristics.

The main differences between the predicate and the TomoTherapy Treatment Delivery System with iDMS are:

1) The predicate includes integral treatment planning and data management subsystems, whereas the TomoTherapy Treatment Delivery System with iDMS is strictly a radiation treatment delivery device.
2) The TomoTherapy Treatment Delivery System with iDMS uses the Treatment Delivery Console (TDC) of the Radixact Treatment Delivery System (last cleared on K161146) in place of the Operator Station (OS) from the predicate, to which the TDC is functionally equivalent.
3) The TomoTherapy Treatment Delivery System with iDMS includes software changes (due to the use of the TDC from the Radixact Treatment Delivery System) to allow it to connect and work compatibly with the Accuray Precision™ Treatment Planning System (last cleared on K171086) and iDMS™ Integrated Data Management System (K161144).

Where there are technological differences between the TomoTherapy Treatment Delivery System with iDMS 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 TomoTherapy Treatment Delivery System with iDMS is presented below:

General Characteristics	**<u>Predicate Device</u> TomoTherapy Treatment System (K121934)**	**<u>Subject Device</u> TomoTherapy Treatment Delivery System with iDMS**
System Configuration	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)

General Characteristics	**Predicate Device** **TomoTherapy Treatment System (K121934)**	**Subject Device** **TomoTherapy Treatment Delivery System with iDMS**
Vault		
Min. Room Dimensions		
Height*	270 cm	Identical to predicate**
Width*	462 cm	Identical to predicate **
Length*	596 cm	Identical to predicate **
Device Dimensions (gantry and couch)		
Height*	252 cm	Identical to predicate **
Width*	280 cm	Identical to predicate **
Length*	466 cm	Identical to predicate **
Weight	4,943 kg	Identical to predicate **
Environment		
Line Voltage	380-480V, 3-Phase	Identical to predicate
Ambient Room Temperature	68-75 ^{o}F (20-24 ^{o}C)	Identical to predicate
Relative Humidity	30%-60%, non-condensing	Identical to predicate
Gantry Mechanical Features		
Degrees of Rotation	Continuous rotation around Y-axis (axes per IEC 61217)	Identical to predicate
Direction of Rotation	Clockwise (as viewed from the foot of the patient couch)	Identical to predicate
Bore Size	85 cm diameter	Identical to predicate
Speed of Rotation		
Treatment	1 to 5 RPM	Identical to predicate
Imaging	6 RPM	Identical to predicate
Radiation Delivery Modes	Helical	Identical to predicate
	Direct	Identical to predicate

General Characteristics	**Predicate Device** **TomoTherapy Treatment System (K121934)**	**Subject Device** **TomoTherapy Treatment Delivery System with iDMS**
Photon Beam		
Accelerator Type	Standing wave	Identical to predicate
RF Source	Magnetron	Identical to predicate
Nominal Energy	6 MV (single energy)	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	Identical to predicate
Collimation	Primary collimation, jaws and multi-leaf collimator (MLC)	Identical to predicate
Imaging		
Field of View	39 cm diameter	Identical to predicate
Dose per MVCT image (typical)	0.5 - 3.0 cGy	Identical to predicate
Slice spacing	1, 2, 3, 4 and 6 mm reconstruction intervals	Identical to predicate
Spatial Resolution	1.6 mm spatial resolution	Identical to predicate

General Characteristics	**Predicate Device** **TomoTherapy Treatment System (K121934)**	**Subject Device** **TomoTherapy Treatment Delivery System with iDMS**
Laser System		
Stationary	Green lasers, identify virtual and actual isocenter	Identical to predicate
Moveable (for patient positioning and registration)	Red lasers, offset from virtual isocenter	Identical to predicate
Patient Couch		
Biocompatibility	Carbon-fiber top	Identical to predicate
Motion		
X-axis	Independent of other axes	Identical to predicate
Y-axis	Coupled with Z-axis (via couch Cobra motion)	Identical to predicate
Z-axis	Coupled with Y-axis (via couch Cobra motion)	Identical to predicate
Power Distribution		
Isolation	Transformer	Identical to predicate
UPS for Data Back-up	Provided	Identical to predicate
Operator Station	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Uses the Treatment Delivery Console (TDC), cleared as part of the Radixact Treatment Delivery System (K161146), which is functionally equivalent to the predicate Operator Station

General Characteristics	**Predicate Device** **TomoTherapy Treatment System (K121934)**	**Subject Device** **TomoTherapy Treatment Delivery System with iDMS**
Machine Control Software	Controls radiation delivery and positioning systems (referred to as the RDS – Radiation Delivery System)	Functionally equivalent to predicate (referred to as the ECS – Embedded Controls Subsystem)
Data Interfaces Operator Station	Provides measurements and status during operation	Functionally equivalent to predicate
Database	Integrated database used for gathering operational data and storage of procedure data	Works with functionally-equivalent external database such as the Accuray iDMS™ Integrated Data Management System (K161144)
Safety Features	Interlock Subsystems	Functionally equivalent to predicate
	Data integrity checking	Functionally equivalent to predicate

***** Dimensions are rounded to the nearest centimeter.

****** Information Source: TomoTherapy Treatment Delivery System with iDMS Technical Specifications

Performance Data

Results of verification and validation testing confirm that the TomoTherapy Treatment Delivery System with iDMS conforms to design specifications and meets the needs of the intended users. Additionally, testing performed by an independent certified testing laboratory demonstrates the device complies with the requirements of applicable FDA recognized consensus safety standards for radiation therapy medical devices. These test results demonstrate that the TomoTherapy Treatment Delivery System with iDMS is as safe and effective, and performs as well as the predicate device.

No animal or clinical tests were required to establish substantial equivalence with the predicate device.

Conclusion

The TomoTherapy Treatment Delivery System with iDMS is substantially equivalent to the predicate device. The intended use, principles of operation, performance specifications and technological characteristics of the TomoTherapy Treatment Delivery System with iDMS are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the TomoTherapy Treatment Delivery System with iDMS in comparison to the cleared predicate device. Further, performance data demonstrate that the TomoTherapy Treatment Delivery System with iDMS has substantially equivalent safety and performance characteristics in comparison to the predicate device. Accordingly, the TomoTherapy Treatment Delivery System with iDMS is substantially equivalent to the predicate device.