



Food and Drug Administration
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Accuray Incorporated
% Shweta Kaushik, Ph.D., RAC
Regulatory Affairs Specialist II
1310 Chesapeake Terrace
SUNNYVALE CA 94089

June 24, 2016

Re: K161136
Trade/Device Name: Precision Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, IYE
Dated: June 7, 2016
Received: June 9, 2016

Dear Dr. Kaushik:

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 over a large, semi-transparent 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)

K161136

Device Name

Precision™ Treatment Planning System

Indications for Use (Describe)

The Precision™ treatment planning system is indicated for creation and assessment of external photon beam irradiation treatment plans for radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. A treatment plan provides an estimate of the dose distribution and the parameters utilized by the radiation delivery system. Plans must be reviewed and approved by qualified medical practitioners prior to delivery.

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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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name, Address, Phone and Fax number of the Applicant

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Contact Person

Shweta Kaushik

Date Prepared

April 21, 2016

Device Name

Device Name: Precision™ Treatment Planning System
Common Name: Radiation therapy treatment planning system
Marketed Trade or Model Name: Precision™ Treatment Planning System
Regulatory Classification Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Regulatory Product Code: MUJ
Classification Panel: Radiology
Regulation Number: CFR 892.5050

Device Description

The Precision™ Treatment Planning System is a radiation therapy planning system used for creation and assessment of treatment plans for delivery by radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery treatment systems. It includes the planning system features of both the currently marketed predicate devices: *CyberKnife*

MultiPlan Treatment Planning System (K150873) and the *TomoTherapy Planning Station (K121934)*. Hence, the Precision Treatment Planning System is intended for treatment planning for multiple platforms:

- Accuray's robotic radiosurgery systems, including but not limited to the CyberKnife® Treatment Delivery System (last cleared K150873).
- Accuray's ring gantry systems, including but not limited to the Radixact™ Treatment Delivery System which is a next generation TomoTherapy® Treatment System (last cleared K121934).

Indications for Use

The Precision™ treatment planning system is indicated for creation and assessment of external photon beam irradiation treatment plans for radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. A treatment plan provides an estimate of the dose distribution and the parameters utilized by the radiation delivery system. Plans must be reviewed and approved by qualified medical practitioners prior to delivery.

Intended Use

The Precision™ treatment planning system is indicated for creation and assessment of external photon beam irradiation treatment plans for radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. A treatment plan provides an estimate of the dose distribution and the parameters utilized by the radiation delivery system. Plans must be reviewed and approved by qualified medical practitioners prior to delivery.

The Precision™ Treatment Planning System is intended to be used by physicians, medical physicists, and dosimetrists to generate radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery treatment plans. Plans may be created with the Precision treatment planning system for delivery using Intensity Modulated Radiation Therapy (IMRT) or 3-D Conformal Radiation Therapy (3DCRT) techniques.

The users will be able to create a plan that satisfies established clinical objectives. For stereotactic radiosurgery, the plan will generally involve delivering a tumoricidal dose to target tissue, while minimizing dose to other tissues. For radiation therapy and

stereotactic radiotherapy, the plan will generally involve delivering a damaging dose to diseased tissue at a level that allows healthy tissue in the target volume to recover, while also minimizing dose to tissue outside the target volume.

The treatment plan with dose distributions and complete delivered dose value along with the input data will be available through a user display or printed report for user review and evaluation against the treatment prescription and established physics models. The treatment plan will then be saved by the user, approved by the qualified medical practitioner, and subsequently delivered by the treatment delivery system.

Technological Characteristics

There is no significant difference between the subject and predicate devices in terms of fundamental scientific technology or principles of operation. During the design of subject device, some modifications or additions were made to the CyberKnife MultiPlan Treatment Planning System to either include the functionality of TomoTherapy Planning Station or to improve the existing functionality/ user interface. A brief summary of the technological characteristics of the subject device in comparison to those of the predicate devices is provided below:

Device Characteristic	CyberKnife MultiPlan Treatment Planning System (K150873) (Primary Predicate Device)	TomoTherapy Planning Station (K121934) (Predicate Device)	Precision Treatment Planning System (Subject Device)
Associated Treatment Delivery System	Determines treatment planning and dose distribution for the CyberKnife System	Determines treatment planning and dose distribution for the TomoTherapy System	Same as predicates as determines treatment planning and dose distribution for both CyberKnife and TomoTherapy Systems
Hardware	PC class workstation	PC class workstation	Same as predicates (PC class workstation)
Image series used	DICOM image series (CT, MR, PET, etc.)	DICOM image series (CT)	Same as predicates (CT, MR, PET, etc.)
Image registration	Rigid image registration	N/A	Same as predicate with added Deformable Fusion

Device Characteristic	CyberKnife MultiPlan Treatment Planning System (K150873) (Primary Predicate Device)	TomoTherapy Planning Station (K121934) (Predicate Device)	Precision Treatment Planning System (Subject Device)
Autosegmentation (VOI contour tool)	Brain, Male Pelvis	N/A	Same as predicate with added Head and Neck Autosegmentation tool
Treatment Machine set-up	Default for CyberKnife System	Default for TomoTherapy System	Same as predicates but with added option to select treatment delivery system if multiple machines are available
Plan Modes	N/A	IMRT, 3DCRT	Same as predicate with added Forward Planning mode
Optimization and dose calculation subsystem	N/A	Separate GPU processing hardware	Same as predicate with GPU integrated into the PC workstation

Performance

The performance test data for Precision Treatment Planning System demonstrates that the user will be able to create, save, review and modify treatment plans with the same or higher level of quality as currently produced by each of the individual predicate treatment planning systems. Thus, Precision Treatment Planning System demonstrates similar performance characteristics to the predicate devices.

Substantial Equivalence

The subject device, Precision Treatment Planning System is substantially equivalent to both predicate devices: CyberKnife MultiPlan Treatment Planning System and TomoTherapy Planning Station in intended use, technological characteristics and performance. The minor differences in technological characteristics raise no new questions of safety or efficacy and the performance data confirms that the Precision Treatment Planning System is as safe and effective as the predicate devices.