Accuray Incorporated
℅ Lizhi Yu
Sr. Manager Regulatory Affairs APAC & AMS
1209 Deming Way
MADISON WI 53717

September 30, 2021

Re: K212794
Trade/Device Name: Accuray Precision® Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: September 1, 2021
Received: September 2, 2021

Dear Lizhi Yu:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212794

Device Name
Accuray Precision® Treatment Planning System

Indications for Use *(Describe)*
The Accuray 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.

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

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ACCURAY

510(k) Summary

K212794

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

Accuray Incorporated
1209 Deming Way
Madison, Wisconsin, 53717

Contact Person

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Date Prepared
September 1, 2021

Device Name

Subject Device Name: Accuray Precision® Treatment Planning System
Marketed Trade or Model Name: Accuray Precision® Treatment Planning System
Common Name: Radiation therapy treatment planning system
Regulation Number: 21 CFR 892.5050
Regulatory Classification Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Regulatory Product Code: IYE, MUJ
Classification Panel: Radiology

Predicate Device Name: Accuray Precision® Treatment Planning System (K171086)

Device Description

The **Accuray Precision® Treatment Planning System** is a radiation therapy planning system used for the creation and assessment of treatment plans for delivery by radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery treatment systems.

The radiation treatment plan is developed by using diagnostic CT (primary image series) and/or secondary images (MR and PET) of the patient previously acquired prior to

treatment and saved into the central database server (iDMS Data Management System). The images are imported from the database server into the Accuray Precision® Treatment Planning System to register/ fuse for dose calculation, and to accurately define/contour regions of interest (target) and the surrounding critical anatomical structures to avoid.

The user (dosimetrist/ medical physicist/ physician) then specifies the treatment delivery machine (CyberKnife or TomoTherapy systems, Radixact systems), treatment delivery mode (e.g., 3DCRT, IMRT) and the patient alignment at the treatment machine. This is followed by specifying the radiation dose criteria for the identified regions of interest, as well as the number of fractions over which this dose is to be administered. After the relevant data has been entered, the user initiates the treatment plan calculation or optimization process. When the treatment plan has been calculated, the user may refine the plan with adjustments to the regions of interest, avoidance structures, and dose criteria and re-optimize the plan.

Once an optimized treatment plan is produced that meets the requirements of the intended therapy, the prescribing physician approves the plan for delivery and the plan is saved on the database server as a treatment delivery plan. The plan reports are also printed for the patient record.

Indications for Use

The Accuray 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 Accuray 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 Accuray 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 Accuray 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.

Comparison of Technological Characteristics with the predicate Device

There is no significant difference between the subject device (Accuray Precision® Treatment Planning System with modifications) and the predicate device (Accuray Precision® Treatment Planning System, last cleared on K171086) in terms of fundamental scientific technology or principles of operation. A brief summary of the technological characteristics of the subject device in comparison to those of the predicate device is provided below:

Device Characteristic	Accuray Precision® Treatment Planning System (K171086) Predicate Device	Accuray Precision® Treatment Planning System With modifications Subject Device
Intended Use	The Accuray 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 Accuray 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 Accuray 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	Identical as predicate

Device Characteristic	Accuray Precision® Treatment Planning System (K171086) Predicate Device	Accuray Precision® Treatment Planning System With modifications Subject Device
	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.	
Indications for Use	The Accuray 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.	Identical as predicate
Associated Treatment Delivery System	Determines treatment planning and dose distribution for the CyberKnife and TomoTherapy Systems	Same as predicate. In this context, TomoTherapy refers to the product line and is inclusive of Radixact
Hardware	PC class workstation	Same as predicate
Dose Calculation Algorithms	Superposition/ Convolution, Ray Tracing, FSPB and Monte Carlo (InCise Multileaf Collimator (MLC) and circular collimators)	Substantially equivalent with minor enhancements
Dosimetry Tests	Absolute Dose specification (CyberKnife Systems) Gamma test specification (CyberKnife) Gamma index (TomoTherapy System)	Identical as predicate
Data Management System	iDMS Data Management System (K161144)	iDMS Data Management System is a component of Accuray Precision® Treatment Planning System

Performance Data

The performance test data for subject device, Accuray Precision® Treatment Planning System with modifications, confirms that the user will be able to create, save, review and modify treatment plans with the same or higher level of quality as compared to the treatment plans created using the predicate device. Software verification and validation was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The results from testing included in the premarket notification demonstrate that the performance characteristics of the subject device are substantial equivalent to the predicate device.

Substantial Equivalence Summary

The subject device, Accuray Precision® Treatment Planning System with modifications, is substantially equivalent to the predicate device, Accuray Precision® Treatment Planning System, in intended use, technological characteristics and performance. The modifications performed to the predicate device do not raise different questions of safety or efficacy. Therefore, the subject device is as safe and as effective as the predicate device.