DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2017

Accuray Incorportaed
% Ms. Jyoti Singh
Regulatory Affairs Specialist
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K170788
Trade/Device Name: CyberKnife® Treatment Delivery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 15, 2017
Received: March 16, 2017

Dear Ms. Singh:

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,

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

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)*
K170788

Device Name
CyberKnife® Treatment Delivery System.

Indications for Use *(Describe)*
The CyberKnife® Treatment Delivery System is indicated for image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

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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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

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, California-94089
Ph: (408) 716-4660
Fax: (408) 789-4249

Contact Person

Jyoti Singh

Date Prepared

March 15, 2017

Device Name

Trade Name: CyberKnife® Treatment Delivery System

Common Name: Radiosurgery/radiotherapy delivery system

Regulation Number: 21 CFR 892.5050

Regulatory Classification Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Regulatory Product Code: IYE

Classification Panel: Radiology

Device Description

The CyberKnife® Treatment Delivery System (CKTDS), subject of this submission, is a computer-controlled radiation treatment delivery system for performing minimally invasive stereotactic radiosurgery and precision radiotherapy. The CyberKnife Treatment Delivery System is intended to work with Accuray Precision™ Treatment Planning System (K161136) and iDMS™ Data Management System (K161144).

The CKTDS uses a 6 MV linear accelerator mounted on a manipulator (robot) and a target locating subsystem to accurately deliver high-energy radiation (1000 MU/minute dose rate) to the treatment target. The target locating subsystem of the treatment delivery system provides X-rays of the treatment area that lets the user know the position of the

target. The CyberKnife® Treatment Delivery System uses skull tracking, fiducial tracking (tracking of implanted radiographic markers), skeletal structure tracking, lung tumor tracking, Lung Optimized Treatment, and Synchrony Respiratory Tracking for dynamic positioning and pointing of the linear accelerator. The fixed aperture, variable aperture, and multileaf collimators are available as various beam-limiting secondary collimators.

Indications for Use

The CyberKnife® Treatment Delivery System is indicated for image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Intended Use

The CyberKnife® Treatment Delivery System is indicated for image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

The CyberKnife® Treatment Delivery System may be used to treat astrocytoma, glioma, skull base tumors, metastases (brain and bony), nasopharyngeal carcinoma, meningioma, acoustic neuroma, schwannoma, pituitary adenoma, hemangioblastoma, craniopharngioma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, and tumors of the neck, spine, pancreas, liver, lungs, ovary, prostate, and bladder. Patients should be examined by a team of physicians to determine if they are candidates for CyberKnife treatment.

Substantial Equivalence

The CyberKnife® Treatment Delivery System is substantially equivalent to the treatment delivery component of the predicate, CyberKnife M6 Systems (cleared under K150873). The intended use for radiologic applications, principles of operation, technological characteristics are the same as the treatment delivery component of the predicate device.

The source energy, beam properties, design, materials and other physical properties of the subject device are the same or equivalent to the treatment delivery component of the predicate device.

Testing was done to verify that all hardware and software perform as designed. Regressing testing was also performed to verify integrity of the existing features. The results from testing included in the premarket notification demonstrate that subject device performance characteristics are equivalent to the treatment delivery component of the predicate device.