K102650

510(k) SUMMARY

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

NOV 17 2010

Name, Address, Phone and Fax number of the Applicant

Accuray Incorporated
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Contact Person

Anne Schlagenhaft

Date Prepared

September 30, 2010

Device Name

Trade Names: CyberKnife VSI™ Robotic Radiosurgery System
CyberKnife® Robotic Radiosurgery System
Common Name: Radiosurgery/radiotherapy treatment planning and delivery system
Classification Name: Medical charged particle radiotherapy device

Device Description

The CyberKnife Robotic Radiosurgery System and CyberKnife VSI Robotic Radiosurgery System are computer controlled medical systems for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy using a treatment radiation generator, linear accelerator, manipulator (robot), and a target locating subsystem to accurately deliver radiation to the treatment target. The target locating system provides X-rays of the treatment area taken by a diagnostic X-ray system that lets the user know the position of the target. The CyberKnife and CyberKnife VSI Systems use skull tracking, fiducial tracking, Xsight® Spine Tracking, Xsight® Lung Tracking, and Synchrony® Respiratory Tracking for dynamic positioning and pointing of the linear accelerator. The system uses a 6 MV linear accelerator to provide a dose rate up to 1000 MU/minute.

Intended Use

The CyberKnife and CyberKnife VSI Systems are intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions anywhere in the body when radiation treatment is indicated.

The CyberKnife Systems 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 and CyberKnife VSI Systems are substantially equivalent to the predicate CyberKnife System. The source energy, beam properties, design, materials and other physical properties are the same or equivalent to the predicate CyberKnife System. Testing included in the premarket notification demonstrated that the performance characteristics of the device are equivalent to the predicate CyberKnife System.

Testing was done to verify that the new tracking software, performs as designed, as well as regression testing to verify integrity of existing features. Archived images from CyberKnife patient lung treatments were used to test tracking performance which proved to be equivalent to the predicate CyberKnife tracking systems.

The intended use, principles of operation, technological characteristics and labeling are the same or equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Ms. Anne Schlagenhaft
Senior Regulatory Affairs Associate
Accuray Incorporated
1301 Chesapeake Terrace
SUNNYVALE CA 94089

NOV 17 2010

Re: K102650
Trade/Device Name: CyberKnife® Robotic Radiosurgery System and CyberKnife VSI™ Robotic Radiosurgery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 13, 2010
Received: September 23, 2010

Dear Ms. Schlagenhaft:
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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

NOV 17 2010

Indications for Use

510(k) Number (if known): K102650
Device Name: CyberKnife® Robotic Radiosurgery System and CyberKnife VSI™ Robotic Radiosurgery System
Indications For Use:

The CyberKnife® Robotic Radiosurgery System and CyberKnife VSI™ Robotic Radiosurgery System are indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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