K091999

SEP 18 2009

510(k) SUMMARY

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

Name, Address, Phone and Fax number of the Applicant

Accuray Incorporated
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Contact Person

Anne Schlagenhaft

Date Prepared

June 30, 2009

Device Name

Trade Name: CyberKnife VSI™ Robotic Radiosurgery System
Classification Name: Medical charged particle radiotherapy device

Device Description

The CyberKnife VSI Robotic Radiosurgery System is a computer controlled medical system 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 CyberKnife VSI uses skull tracking, fiducial tracking, Xsight® Spine Tracking, Xsight® Lung Tracking, and Synchrony® Respiratory Tracking for dynamic positioning and pointing of the linear accelerator.

Intended Use

The CyberKnife VSI Robotic Radiosurgery System is 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.

Substantial Equivalence

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

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

SEP 18 2009

Ms. Anne Schlagenhaft
Senior Regulatory Affairs Associate
Accuray, Inc.
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K091999
Trade/Device Name: 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: August 21, 2009
Received: August 24, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091999
Device Name: CyberKnife VSI™ Robotic Radiosurgery System
Indications For Use:

The CyberKnife VSI™ Robotic Radiosurgery System is 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 ✓ 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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091999