



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

Accuray Incorporated  
% Dr. Shweta Kaushik  
Regulatory Affairs Specialist  
1310 Chesapeake Terrace  
SUNNYVALE CA 94089

July 1, 2015

Re: K150873

Trade/Device Name: Cyberknife® M6™ Systems

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Product Code: IYE

Dated: April 1, 2015

Received: April 2, 2015

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,



Robert Ochs, Ph.D. For  
Acting 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)

K150873

Device Name

CyberKnife® M6™ Systems

Indications for Use (Describe)

The CyberKnife® M6™ Systems 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.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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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) 716-4600  
Fax: (408) 789-4249

### **Contact Person**

Shweta Kaushik

### **Date Prepared**

May 28, 2015

### **Device Name**

Trade Names: CyberKnife® M6™ Systems  
Common Name: Radiosurgery/radiotherapy treatment planning and delivery system  
Classification Name: Medical charged particle radiotherapy device  
Classification C.F.R. Section: 21CFR892.5050, Class II  
Product Code: IYE

### **Device Description**

The CyberKnife M6 Systems are computer-controlled medical systems for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy. They use 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 provides X-rays of the treatment area that lets the user know the position of the target.

The CyberKnife M6 Systems use 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, variable aperture and multileaf collimators are available as various beam-limiting secondary collimators.

**Intended Use**

The CyberKnife® M6™ Systems 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.

The CyberKnife M6 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® M6™ System with InCise™ 2 Multileaf Collimator is substantially equivalent to the predicate CyberKnife® M6™ System with InCise™ Multileaf Collimator. The intended use, principles of operation, technological characteristics and labeling are the same or equivalent to 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 predicate CyberKnife M6 System.

Testing was done to verify that the all hardware and software perform as designed, as well as regression testing to verify integrity of existing features. The results from testing included in the premarket notification demonstrated that the performance characteristics of the device are equivalent to the predicate system.