K020294

APR 2 2 2002

Tab 4

Premarket Notification [510(k)] Summary

January 25, 2002

Trade Name:	Motion Tracking System
Common Name:	Linear Accelerator for Radiation Therapy
Classification Name:	Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)
Manufacturer's Name:	Accuray Incorporated
Address:	570 Del Rey Avenue Sunnyvale, CA 94085
Corresponding Official:	Donald E. Caddes
Title:	President and COO
Telephone:	408-522-3740
Fax:	408-522-3749
Predicate Devices:	Accuray CyberKnife® System, K011024 and Varian Medical Systems RPM Respiratory Gating System, K983629.

Device Description: Presently, irradiation of lesions that move during breathing, such as those located in the lung or near the diaphragm, would typically be performed during patient breath-holds. The Motion Tracking System option to the CyberKnife® System is designed to treat lesions while they are moving during the respiratory cycle. This offers the ability to reduce normal tissue exposure by using smaller irradiation margins, shorten treatments, increase accuracy and provide more comfort for the patient.

During motion tracking operation, a correspondence between surface (e.g. thorax/abdomen) movements and movement of the target lesion is developed prior to the start of treatment and is regularly updated during treatment each time the CyberKnife system acquires a new pair of x-ray images. This correspondence is then used to estimate lesion position in real time by monitoring surface movement during treatment.

Motion Tracking provides the CyberKnife system with the capability to monitor the patient's respiration and command the robot manipulator to compensate for

the treatment target motion within the body, in real-time, while the radiation is being delivered.

The Motion Tracking System includes a sensor assembly, tracking targets, a cable junction box, and a controller.

Intended Use: The Motion Tracking System is an option to the CyberKnife System and is intended to enable dynamic image guided stereotactic radiosurgery and precision radiotherapy of lesions, tumors and conditions that move under the influence of respiration.

Technological Characteristics: Refer to Tab 9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

Mr. Donald E. Caddes
President and COO
Accuray Incorporated
570 Del Rey Avenue
SUNNYVALE CA 94085

Re: K020294
Trade/Device Name: Motion Tracking System
Respiratory Tracking Accessory
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation system
Regulatory Class: II
Product Code: 90 IYE
Dated: January 25, 2002
Received: January 28, 2002

Dear Mr. Caddes:

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); 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.

This letter will allow you to begin marketing your device as described in your 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K020294

Device Name: Motion Tracking System

Indications for Use:
To provide an option to the CyberKnife System which will enable dynamic image guided stereotactic radiosurgery and precision radiotherapy of lesions, tumors and conditions that move under the influence of respiration.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David A. Clayton

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020294