SEP - 3 2003

K032345

APPENDIX F. 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
570 Del Rey Avenue
Sunnyvale, California 94085
Ph: (408) 522-3740
Fax: (408) 522-3749

Contact Person

Anne Schlagenhaft

Date Prepared

July 29, 2003

Device Name

Trade Name:CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy
Classification Name: Medical linear accelerator

Device Description

The CyberKnife 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 sophisticated target locating subsystem to accurately deliver radiation to the treatment target. The CyberKnife System uses skull tracking and tracking of implanted fiducials for dynamic positioning and pointing of the linear accelerator.

Intended Use

The CyberKnife System for Stereotactic Radiosurgery/Radiotherapy is intended to provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Substantial Equivalence

The CyberKnife System with the FAST algorithm is substantially equivalent to the predicate device. The intended use, principles of operation, technological characteristics and labeling are the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2003

Ms. Anne Schlagenhaft
Senior Regulatory Affairs Associate
Accuray Incorporated
570 Del Rey Avenue
SUNNYVALE CA 94085

Re: K032345
Trade/Device Name: CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle Radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 29, 2003
Received: August 4, 2003

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); 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 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K 032345

Device Name: CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy

Indications For Use:

The CyberKnife 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

(Optional Format 1-2-96)

David G. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032345