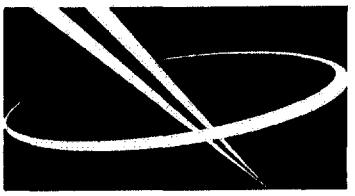
JUL 14 1999

K984563



ACCURAY

510(k) Summary of Safety and Effectiveness

Establishment:	Accuray Incorporated 570 Del Rey Avenue Sunnyvale, CA 94086 (408) 522-3740
Contact:	Luanne Termeer Regulatory Affairs Manager
Summary Date:	12/20/98
Device Name:	The CyberKnife™ System for Stereotactic Radiosurgery/Radiotherapy
Predicate Device:	Varian Clinac™ 600SR, K913174
Device Description:	The CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy is a treatment planning, imaging, and treatment delivery system for image-guided stereotactic radiosurgery and precision radiotherapy. The treatment planning system provides 3-dimensional viewing of the patient anatomy with appropriate dose calculation of the target volume and surrounding tissue structures. The imaging system provides real-time, orthogonal x-ray images of the patient in the treatment position to verify treatment position and accuracy and provides information suitable for dynamically positioning and pointing a linear accelerator. The treatment delivery system consists of a linear accelerator which provides 6 MV x-rays. A six-access manipulator provides automated positioning and pointing of the linear accelerator. The treatment couch provides positioning of the patient.

Intended Use: The CyberKnife system is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain, base of skull (BOS) and cervico-thoracic spine (CTS), head and neck.

Summary of Technological Characteristics:

See the Feature Comparison Chart on the following page.

FEATURE COMPARISON CHART

Feature	Varian Clinac 600SR – K913174	Accuray CyberKnife® System For Stereotactic Radiosurgery/Radiotherapy
Use	Provide x-radiation for use in stereotactic radiosurgery. Treatment Planning with X-Knife, K923522	Provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy
Single dose and fractionated treatments	Yes	Yes
Microwave band	S	X
X-ray energy	6MV (standing wave linac)	6 MV (standing wave linac)
Dose rate	800 cGy/min	300 cGy/min
Microwave generator	High power magnetron	High power magnetron
Bending magnet	In-line	In-line
Isocenter floor height	128 cm	127 cm (nominal isocenter, system is not isocentric)
SAD	100 cm	80 cm
End of collimator to isocenter	23 cm	40 cm
Source/target positioning	Two-axis manipulator	Six-axis manipulator
Treatment table	Rotates patient about third axis	Stationary
Mechanical Isocenter Accuracy	≥ 0.10 cm radius circle	≥ 0.05 cm RMS for all treatment nodes
Dosimetry system reproducibility with position	± 2% or 1 MU whichever is greater at any fixed gantry angle	± 3% or 3 MU which ever is greater at any fixed treatment node
Beam collimation	Heavy metal secondary collimators allow selection of narrow beams sizes 12.5 to 40 mm (12 steps)	Heavy metal secondary collimators allow selection of narrow beams sizes 5 to 60 mm (12 steps)
Head restraint	BRW or GTC head ring	Laitenen Stereoadapter headframe, K881131 Uniframe head immobilization system, K933227
Target location reference	Metal localization rods connected to headframe	Patient's skull
Treatment Planning System (TPS)	Yes	Yes
TPS platform	HP715/75, 64MB/1GB	SGI 440, 128MB/2GB
Safety interlocks	Yes	Yes
Emergency stop	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Luanne Ng
Regulatory Affairs Manager
Accuray, Inc.
570 Del Rey Avenue
Sunnyvale, CA 94086

Re: K984563
Trade Name: CyberKnife™ System for Steriotactic Radiosurgery/Radiotherapy
Regulatory Class: II
Product Code: 90-IWB and 90-MUJ
Dated: April 15, 1999
Received: April 16, 1999

Dear Ms. Ng:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984563

Device Name The CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy

Indications For Use: To provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain, base of skull (BOS), cervico-thoracic spine (CTS), head and neck.

(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, ENT,
and Radiological Devices
510(k) Number K984563

Prescription Use ✓ OR Over-The Counter Use_____
Per 21 CFR 801.109