K973441

SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

APR - 1 1998

19.1 SUBMITTER INFORMATION

a. Company Name:	Elekta Instrument, AB
b. Company Address:	Birger Jarlsgatan 53 Stockholm, Sweden
c. Company Phone: Company Facsimile:	(011) 46 8 587 254 00 (011) 46 8 587 255 00
d. Contact Person:	Sverker Glans Vice President Quality/Regulatory Affairs Elekta Instrument, AB
e. Date Summary Prepared:	September 2, 1997

19.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Leksell GammaPlan®
b. Classification Name:	Radionuclide radiation therapy system. CFR 892.5750

19.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Elekta Instrument, AB	Leksell GammaPlan®	K914808	January 23, 1992

19.4 DEVICE DESCRIPTION

The Leksell GammaPlan® is a computer based dose planning system specifically designed for use with the Leksell Gamma Knife. The Leksell GammaPlan is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. Digital images from CT or MR scanners, or angiograms are imported and processed for treatment planning. Patient treatment protocols are based on single or multiple targets and alternative treatment plans can be generated by the GammaPlan.

19.5 SUBSTANTIAL EQUIVALENCE

The Leksell GammaPlan® is substantially equivalent to the previous version of the Leksell GammaPlan currently in commercial distribution by Elekta Instrument, AB, in terms of achieving a safe and accurate simulation or plan of stereotactic Leksell Gamma Knife radiosurgery/radiation therapy.

The fundamental algorithm principle of calculation and other technical characteristics are the same as that of the predicate device.

19.6 INTENDED USE

The Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with the Leksell Gamma Knife®. The Leksell GammaPlan® is intended to beused for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. It processes the inputs from the health care professionals such that the desired radiation dose is provided by the Leksell Gamma Knife to a precisely defined target area within the cranium.

19.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices has been completed. Both the original and upgraded versions of the Leksell GammaPlan® use the same algorithm principle. Calculation of the radiation dose for the treatment plan and overlay of the isodose curve is the same in the new version, as in the predicate device. The computer workstation has remained the same in the upgraded version. Image input from CT, MR and AI, modalities have remained the same.

19.8 PERFORMANCE DATA

The Leksell GammaPlan® has been demonstrated to perform as intended. Testing of the software includes Module, Integration and System testing. All test results have been included in Section 14 of this notification.

19.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 1998

Sverker Glans
Elekta Instrument, AB
c/o Carol Patterson
Consultant for Elekta Instrument, AB
18140 Smokesignal Drive
San Diego, CA 92127

Re: K973441
Leksell GammPlan (Radionuclide Radiation Therapy Planning System)
Dated: January 8, 1998
Received: January 12, 1998
Regulatory class: II
21 CFR 892.5750/Procode: 90 IWB

Dear Ms. Glans:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA K973441

Device Name: Leksell GammaPlan®

Indications For Use: The Leksell GammaPlan (LGP) is designed for use with the Leksell Gamma Knife manufactured by Elekta Instrument, AB. The Leksell GammaPlan is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. It processes the inputs of the health care professionals (Neurosurgeons, Radiation Therapists, Radiation Physicists) such that the desired radiation dose is provided by the Leksell Gamma Knife to a precisely defined target area within the cranium.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

David H. Reynolds

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973441