MAY 21 1999

K984328

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.

19.1 SUBMITTER INFORMATION

a.	Company Name:	Elekta Instruments, AB
b.	Company Address:	Birger Jarlsgatan 53, S-103, 93 Stockholm, Sweden
c.	Company Phone: Company Fax:	(011) 46 8 5872 54 00 (011) 46 8 5872 55 00
d.	Contact Person:	Sverker Glans Vice President Quality and Regulatory Affairs Elekta Instruments, AB
e.	Date Summary Prepared:	November 20, 1998

19.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Leksell® Gamma Knife Target System Model 24001
b.	Classification Name:	Radionuclide Radiation Therapy Device 21 CFR 892.5750

19.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Elekta Instruments	Leksell Gamma Unit Model 23004, Type B	K924849	November 20, 1995

19.4 DEVICE DESCRIPTION

The Leksell® Gamma Knife Target System is an upgraded version of the currently available Leksell® Gamma Knife device. The device is intended for the stereotactic irradiation of intracranial structures and is composed of seven basic components. The Leksell® Gamma Knife Target System receives data from the Leksell Gamma Plan software. The Target System is composed of a Computerized Control System, Automatic Positioning System, Couch, Radiation Unit and Patient Surveillance System. The patient's head is fixated by the Leksell Stereotactic Coordinate Frame.

19.5 SUBSTANTIAL EQUIVALENCE

The Leksell® Gamma Knife Target System Model 24001 is substantially equivalent to previous version of the Leksell® Gamma Knife Model 23004 currently in commercial distribution by Elekta Instruments. The Leksell® Gamma Knife Target System and the predicate device are both indicated for the stereotactic irradiation of intracranial structures.

The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison charts provided in this 510(k) submission.

19.6 INTENDED USE

The Elekta Instruments Leksell® Gamma Knife Target System Model 24001 is intended for the stereotactic irradiation of intracranial structures.

19.7 TECHNOLOGICAL CHARACTERISTICS

A complete comparison of the technological characteristics of the predicate is provided within this submission. Both the predicate and Target System are composed of the same radiation unit using Cobalt 60 through 201 collimator sources. The Target System and the predicate receive treatment planning data from the Leksell® Gamma Plan software program. In both devices, the patient's head is fixated by the Leksell® Stereotactic Coordinate Frame.

19.8 PERFORMANCE DATA

The Leksell® Gamma Knife Target System has been demonstrated to perform as intended with accuracy and repeatability. The Leksell® Gamma Knife Target System has been tested on the system and subsystem level. Through testing of the software and hardware components of the device have also been completed. Integration testing and complete system testing have also been performed. Results of performance testing, software and hardware testing of the Leksell® Gamma Knife Target System have been included in Sections 13, 15, and 16 of this submission.

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

MAY 21 1999

Elektra Instruments AB
C/O Carol Patterson
Consultant
18140 Smokesignal Drive
San Diego, California 92127

RE: K984328
Gamma Knife
Dated: May 17, 1999
Received: May 18, 1999
Regulatory Class: II
21 CFR 892.5750/Procode: 90 IWB

Dear Ms. Patterson:

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

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA K984328

Device Name: Elekta Leksell® Gamma Knife Target System Model 24001

Indications for Use: The Leksell® Gamma Knife Target System Model 24001 is a teletherapy device indicated for use in the stereotactic irradiation of intracranial structures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Eggerm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984328

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)