

Elekta Instruments AB
Response to 510(k) #K972324 Deficiencies
February 16, 1998

MAR - 2 1998

K972324

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.

18.1 SUBMITTER INFORMATION

- | | | |
|----|------------------------|---|
| a. | Company Name: | Elekta, AB |
| b. | Company Address: | Birger Jarls gatan 53, S-103, 93
Stockholm, Sweden |
| c. | Company Phone: | (011) 46 8402 5400 |
| | Company Fax: | (011) 46 8402 5500 |
| d. | Contact Person: | Sverker Glans
Vice President
Quality and Regulatory Affairs
Elekta, AB |
| e. | Date Summary Prepared: | April 14, 1997 |

18.2. DEVICE IDENTIFICATION

- | | | |
|----|-------------------------|--|
| a. | Trade/Proprietary Name: | Leksell Stercotactic System |
| b. | Classification Name: | Stereotaxic Instrument and Accessories |

Elekta Instruments AB
Response to 510(k) #K972324 Deficiencies
February 16, 1998

18.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Radionics	Cosman-Robert-Wells Stereotactic System	K934523	February 8, 1995
Leibinger & F.L. Fischer	ZD Neurosurgical Localizing Unit	K892425	March 23, 1990

18.4 DEVICE DESCRIPTION

The Leksell Stereotactic System is a stereotaxic instrument and accessories which functions on the center-of-the-arc principle. The basic components of the system are a cartesian coordinate frame and a semi-circular arc. The system has been developed as a modular design with dedicated components and a range of optional accessories. Accessories are available for stereotactic micro-surgery and functional interventions, target localization, diagnostic and therapeutic procedures, and Gamma Knife surgery.

18.5 SUBSTANTIAL EQUIVALENCE

The Leksell Stereotactic System is substantially equivalent to other stereotactic systems currently in commercial distribution by Radionics and Leibinger & Fischer in terms of intended use for localization (spatial reference) for cranial surgery using X-Ray, or CT and MRI image data.

Elekta Instruments AB
Response to 510(k) #K972324 Deficiencies
February 16, 1998

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.

18.6 INTENDED USE

The Elekta Leksell Stereotactic System and Accessories is intended for localization (spatial reference) for cranial surgery using X-Ray, or CT and MRI image data.

18.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices is provided within this submission.

18.8 PERFORMANCE DATA

The Leksell Stereotactic System has been demonstrated to perform as intended with accuracy and repeatability. The system have been shown to be compatible when used in MR scanners of low frequencies. Complete results of performance testing of the Leksell Stereotactic System have been included the 510(k) submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol Patterson
Consultant for Elekta Instruments AB
Patterson Consulting Group, Inc.
18140 Smokesignal Drive
San Diego, California 92127

MAR -2 1998

Re: K972324
Trade Name: Leksell® Stereotactic System
Regulatory Class: II
Product Code: HAW
Dated: December 1, 1997
Received: December 2, 1997

Dear Ms. Patterson:

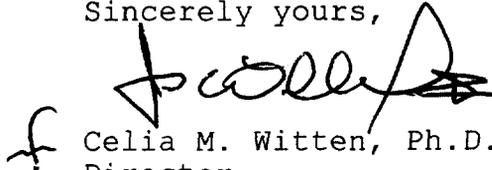
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 requirement, 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 pre-market 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) 594-4595. 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/dsmamain.html>".

Sincerely yours,



f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Elekta Instruments AB
Response to 510(k) #K972324 Deficiencies
February 16, 1998

INDICATIONS FOR USE

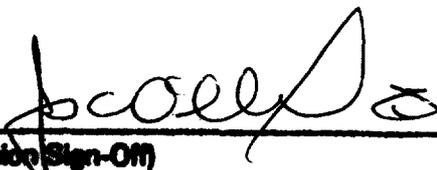
510(k) Number: ~~To Be Assigned By FDA~~ **K972324**

Device Name: Elekta Leksell® Stereotactic System

Indications For Use: The Leksell Stereotactic System is a system intended for localization (spatial reference) for cranial surgery using X-Ray, or CT and MRI image data.

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 General Restorative Devices
510(k) Number K972324

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____