K992882

SEP 24 1999

SECTION 18: 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 Instruments, AB
b.	Company Address:	Birger Jarlsgatan 53, S-103 93 Stockholm, Sweden
c.	Company Phone: Company Facsimile:	(011) 46 8 5872 54 00 (011) 46 8 5872 55 00
d.	Contact Person:	Sverker Glans Vice President Quality and Regulatory Affairs
e.	Date Summary Prepared:	August 24, 1999

18.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Leksell® Image Guidance Surgical System
b.	Classification Name:	Stereotaxic Instrument 21 CFR 882.4560

18.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Elekta Instruments, AB	Leksell® Image Guidance Surgical System	K973684	03/31/98
BrainLAB	Vector Vision^2	K983831	05/19/99

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18.4 DEVICE DESCRIPTION

The Leksell® Image Guidance Surgical System (LIGS) is intended for use in cranial and spinal neurosurgical procedures to provide image guidance based on preoperative images which are visualized interactively with the aid of surgical tools. The LIGS System was cleared for commercial distribution under K973684 on March 31, 1998. The purpose of this special premarket 510(k) notification is to describe the changes in product specifications and system modifications. The LIGS System has not changed in its functionality or its indications for use. Technological enhancements have been made to the ViewScope/Elekta Insight Localization System and Surgical Tools. As a result of these enhancements, the software and instruction manuals have also been updated.

18.5 SUBSTANTIAL EQUIVALENCE

The Leksell® Image Guidance Surgical System with its proposed modifications, is substantially equivalent to the current Leksell Image Guidance Surgical System and the BrainLAB Vector Vision^2.

The fundamental technical characteristics of the LIGS System are similar to those of the predicate devices. The functionality and the indications for use have not changed with the proposed modifications. The addition of the wireless probe feature and use of illuminator infrared camera and universal instrument adapter is equivalent to the features found in the BrainLAB Vector Vision^2 predicate device. The Indications for Use for the LIGS System is also is equivalent to the BrainLAB Vector Vision^2 predicate device.

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18.6 INDICATIONS FOR USE

The Leksell® Image Guidance Surgical System (LIGS) is indicated for use in cranial and spinal neurosurgical procedures to provide image guidance based on preoperative images which are visualized interactively with the aid of surgical tools.

18.7 TECHNOLOGICAL CHARACTERISTICS

Modifications have been made to the Leksell® Image Guidance Surgical System in regards to the Elekta Insight/ViewScope models. The localization technology has been enhanced to include an illuminator infrared camera and reflective spheres on the instruments, allowing for wireless probe options. In addition, the surgical tools have been enhanced to include a Universal Instrument Adapter for fixation to the user's instruments. Comparison of the technological characteristics to those of the predicate devices has been provided in this submission.

18.8 PERFORMANCE DATA

Performance testing was conducted on the Elekta Insight/ViewScope 2.5. System and component testing was completed based on product specifications and hazard effects determined from the risk analysis. Performance testing on simulated cranial and spinal models was conducted for product accuracy and repeatability. All results of testing was found to be acceptable. The Leksell® Image Guidance Surgical System with the proposed modifications performed as intended.

18.9 510(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

SEP 24 1999

Elekta Instruments, AB
C/o Ms. Carol Patterson
Consultant
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, California 92630

Re: K992882
Trade Name: Leksell® Image Guidance Surgical System
Regulatory Class: II
Product Code: HAW
Dated: August 24, 1999
Received: August 26, 1999

Dear Ms. Patterson:

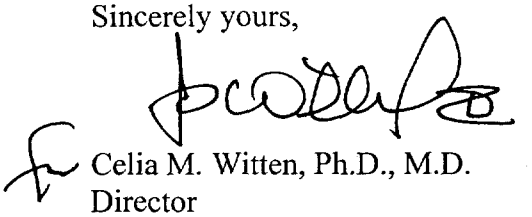
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

K992882

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Leksell® Image Guidance Surgical System

Indications for Use: The Leksell® Image Guidance Surgical System (LIGS) is intended for use in cranial and spinal neurosurgical procedures to provide image guidance based on preoperative images which are visualized interactively with the aid of surgical tools.

(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 K992882

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