 K973684

MAR 31 1998

SECTION 21 510(K) SUMMARY

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

SECTION 21.1 SUBMITTER INFORMATION

a.	Company Name:	Elekta Instruments AB
b.	Company Address:	Birger Jarlsgatan 53 Stockholm, Sweden S-103 93
c.	Company Phone: Company Facsimile:	(011) 46 8402 5400 (011) 46 8402 5500
d.	Contact Person:	Sverker Glans Vice President Quality and Regulatory Affairs Elekta Instruments AB

SECTION 21.2 DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Leksell® Image Guidance Surgical System (LIGS)
b.	Common Name	Neurological Image Guided Surgical System
c.	Classification Name:	Stereotaxic Instrument Computed Tomography System
d.	Device Class:	Class II (per 21 CFR 882.4560, 21CFR 892.1750)

SECTION 21.3 IDENTIFICATION OF PREDICATE DEVICES

Table 21.1 provides relevant information on the predicate devices for the LIGS System.

Table 21.1
LEKSELL® IMAGE GUIDANCE SURGICAL SYSTEM PREDICATE DEVICES

DEVICE NAME	COMPANY	510(K) NUMBER	510(K) CLEARANCE DATE
Elekta Leksell® Image Guidance System (LIGS)	Elekta Instruments AB	K961639	26-July-96
ISG Family of Viewing Wands® (cranial applications)	I.S.G. Technologies, Inc.	K960714	29-May-96
ISG Family of Viewing Wands® (spinal applications)	I.S.G. Technologies, Inc.	K970865	4-June-97

SECTION 21.4 DEVICE DESCRIPTION

The Leksell® Image Guidance Surgical System (hereafter the LIGS System) which is the subject of this 510(k) Premarket Notification is a device System intended for use in neurosurgical procedures to provide image guidance based upon preoperative images which are visualized interactively with the aid of surgical tools. The LIGS System imports Computer Tomography (CT) and Magnetic Resonance (MR) images and provides a visual display of the images for pre-planning surgical paths. The images and pre-planned surgical paths can be viewed at a computer workstation in the operating room. The LIGS System is integrated with a Measurement System, which allows the patient in the operating room environment to be correlated with the diagnostic images

obtained pre-operatively. The LIGS System may then be used for visual or instrumentation guidance during the surgical procedure.

The LIGS System is a modular System comprised of a set of components which may be used in conjunction with three basic Models of system configuration interfaced with a Measurement (position tracking) System:

1. The SurgiScope® Model is configured around a motorized ceiling mounted Integrated Tool Support System with integrated tool support software.
2. The ViewScope® Model is configured for use with a manual Floorstand Microscope System.
3. The FreeHand Model allows for the tracking of surgical tools without the use of a microscope.

The LIGS System consists of 6 major components that may be combined in different permutations in the SurgiScope®, ViewScope®, and proposed FreeHand Models. The six primary components of the LIGS System may be combined in various configurations, depending upon the features desired by the customer. Table 21.2 summarizes the configuration options of the three models of the LIGS System.

Table 21.2

Model Configurations of LIGS System

Component of LIGS	LIGS Model		
	ViewScope®	SurgiScope®	FreeHand
ScopePlan® Imaging System with Computer Workstation	R	R	R
Intra-Operative Software	R	R	R
Measurement System	R	R	R
Integrated Tool Support System	N/A	R	N/A
Floorstand Microscope System	R	N/A	N/A
FreeHand Tool Tracking System	O	O	R

R=Required
O=Optional
N/A=Not Available

Sections 20.4.1-20.4.6 provide an overview of each component of the LIGS System.

SECTION 21.4.1 SCOPEPLAN® IMAGING SYSTEM WITH COMPUTER WORKSTATION

Referring to Table 21.2, the Leksell® ScopePlan® Imaging System is a software based technology which provides surgical planning based upon Computer Tomography (CT), Magnetic Resonance Imaging (MRI), or other currently used 2D and 3D imaging techniques. ScopePlan® also provides for the retrieval of surgical planning studies and imaging during the surgical procedure, image correlation with a defined point (such as the microscope focus, probe tip, or instrument position and orientation), and image retrieval subsequent to the surgical procedure. ScopePlan® is to be used with specified commercially available surgical microscopes and accessories.

ScopePlan® is supplied with a Hewlett-Packard C110 (or equivalent) computer running a Unix operating system. The Workstation includes a hard disk, a graphics board, and a high-resolution color monitor. A second computer Workstation may be installed in a separate location for pre-surgical review of patient images, and planning of the surgical intervention.

SECTION 21.4.2 INTRA-OPERATIVE SOFTWARE

All Models of LIGS allow the surgeon to proceed through the surgical intervention by analyzing images derived from the ScopePlan®, planning the surgical intervention, and then monitoring the intervention at a computer workstation in the Operating Room. The Intra-Operative Software allows the surgeon to display, manipulate, and process images from the ScopePlan®, and interact with the data electronically to derive corroborative information related to the specific anatomy of the patient. The software display is a menu-driven Graphical User Interface, which allows the surgeon to recall to the screen images and surgical trajectories created with ScopePlan®. Image tracking features of the software allow the surgeon to conduct measurement/calibration check of the FreeHand instruments, conduct registration of the patient anatomy to the ScopePlan® image datasets, and display the position and orientation of the FreeHand Instrument on the ScopePlan® images during the conduct of the surgical intervention.

SECTION 21.4.3 MEASUREMENT SYSTEM

The Measurement System is an infrared detection system, which is comprised of locators attached to the patient and tools, infrared detectors, a registration probe, and a processing unit. The locators and the probe contain infrared Light Emitting Diodes (LED's). The system accurately locates and continually tracks the patient, and simultaneously tracks the location of the tool of interest (microscope or FreeHand tool).

SECTION 21.4.4 INTEGRATED TOOL SUPPORT SYSTEM

The Integrated Tool Support System (ITS) is a motorized, manually operated, computer-monitored system that is mounted on the ceiling of the operating room. The ITS supports surgical tools, primarily a surgical microscope, during surgical procedure. The surgeon, or other medical professional, activates electromechanical components to position and adjust the microscope during surgery. The location of the microscope focus may be tracked and displayed on the ScopePlan® images. The ITS is the heart of the SurgiScope® Model of LIGS, and is only available with the SurgiScope® Model.

SECTION 21.4.5 FLOORSTAND MICROSCOPE SYSTEM

The Floorstand Microscope System is a manual floorstand with mounted microscope. The location of the microscope focus may be tracked and displayed on the ScopePlan® images. The ViewScope® Model of the LIGS System is provided with the floorstand microscope.

SECTION 21.4.6 FREEHAND TOOL TRACKING SYSTEM

The FreeHand Tool Tracking System consists of commercially available hand-held instruments, guides, and probes for cranial and spinal applications which are tracked by the Measurement System via locating devices (LED's) embedded in either the instrument handle, or a specially designed "tracker" attached to the instrument. This allows for the use of the existing Measurement System to localize the tip position and spatial orientation of the hand-held instruments. An interface with the ScopePlan® provides for visual feedback to the surgeon by displaying the instrument location as an image on the ScopePlan.

The FreeHand Tool Tracking System is designed as a component of the LIGS System for use with either the ViewScope® Mode or the SurgiScope® Model. Additionally, customers may desire the FreeHand surgical options without the use of a microscope. In

this event, the Freehand Tool Tracking System can be delivered as a separate Model of the LIGS System, without any microscope.

The modified LIGS System described in this Premarket Notification includes all of the safety features of the predicate device, as well as a number of additional safety features affiliated with the FreeHand Tool Tracking System.

SECTION 21.5 INTENDED USE

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

SECTION 21.6 TECHNOLOGICAL CHARACTERISTICS

The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison chart provided in this 510(k) submission. Differences that exist between these systems relate to physical appearance and materials that do not affect the relative safety or effectiveness of the device.

SECTION 21.7 PERFORMANCE DATA

Validation and verification studies were conducted to evaluate the performance characteristics of the Leksell® Image Guidance Surgical System. The results of these studies demonstrated that the Leksell® Image Guidance Surgical System is capable of safely and accurately performing the stated intended use.

SECTION 21.8 510(K) CHECKLIST

The Premarket Notification for the Leksell® Image Guidance Surgical System contains all the information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in the submission.

SECTION 20.9 CONCLUSIONS DRAWN FROM STUDIES

The results of performance testing demonstrate that the Leksell® Image Guidance Surgical System is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1998

Ms. Carol L. Patterson
Official Correspondent for Elekta AB
c/o Patterson Consulting Group
18140 Smokesignal Drive
San Diego, California 92630

Re: K973684
Trade Name: Elekta Leksell® Image Guidance Surgical System
Regulatory Class: II
Product Code: HAW
Dated: January 15, 1998
Received: January 20, 1998

Dear Ms. Patterson:

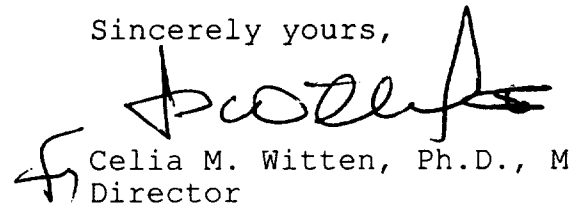
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K973684

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Elekta 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 K973684

Prescription Use √ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)