

ORIGINAL 510(k) SUBMISSION
LEKSELL IMAGE GUIDANCE SURGICAL SYSTEM

K961639

JUL 26 1996

SECTION 20

SUMMARY OF SAFETY AND EFFECTIVENESS

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

20.1 SUBMITTER INFORMATION

- A. Company Name: Elekta Instrument AB
- B. Company Address: Birger Jarlsgatan 53
Stockholm, Sweden S-103 93
- C. Company Phone: (011) 46 8 402 54 00
- D. Contact Person: Sverker Glans
Vice President
Quality and Regulatory Affairs
Elekta Instrument AB
- E. Date Summary Prepared: April 26, 1996

20.2. DEVICE IDENTIFICATION

- A. Trade/Proprietary Name: Leksell Image Guidance Surgical System
- B. Classification Name: Stereotactic Accessory

20.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date</u> <u>Cleared</u>
Elekta Instruments AB	SurgiPlan	K943468	1-20-95
DeeMed Internations	Microscope Support System (MSS)	K920689	11-12-93
Surgical Navigation Technology	Stealth System	K954276	1-24-96
Zeiss	Zeiss Multiple Coordinate Manipulator System (MKM)	K942233	7-1-94

20.4. DEVICE DESCRIPTION

The Leksell Image Guidance Surgical System (LIGS) device provides image guidance in surgical procedures. The LIGS System imports CT/MRI images and provides a visual display of the images for preplanning surgical paths which are used for guidance during the surgical procedures.

The LIGS System is a modular system which includes an interface with a measurement system used with a manual microscope (ViewScope) or with a motorized microscope tool support system (SurgiScope).

The main components of the LIGS System are:

- ScopePlan

ScopePlan provides surgical preplanning based on Computer Tomography (CT), Magnetic Resonance Imaging (MRI) or other current

2D and 3D modalities, retrieval of preplanning studies and imaging during the surgical procedure, image correlation with a defined point and image retrieval subsequent to the surgical procedure.

The ScopePlan is to be used with specified commercially available surgical microscopes and accessories.

- **Measurement System**

The measurement system is an infra-red detection system which is comprised of locators attached to the patient and tool, infra red detectors, a probe and a processing unit. The locators and the probe contain infra red emitting LED's. The system accurately locates and continually tracks the patient and the tool (typically a microscope).

- **Tool Support System**

There are two types of tool support systems which are used with the LIGS System:

- **Standard Floor Stand Microscope Support**

- **SurgiScope Integrated Tool Support System**

The SurgiScope Integrated Tool Support System is a motorized manually operated, computer-monitored device module which is mounted on the ceiling of the operating room. The device holds in place surgical tools, typically a surgical microscope, during operative procedures. The Surgeon, or other medical expert, activates

electromechanical components to position and adjust the microscope during an operation. The user has complete control of the microscope tool during all phases of the procedure and must initiate activation and continuously activate by depressing a push button on the microscope handle in order for the system to operate.

20.5 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.

20.6 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 which do not affect the relative safety or effectiveness of the device.

20.7 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.

20.8 510(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.