K013861

DEC 0 6 2001

SECTION 17: 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.

17.1 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:	November 19, 2001

17.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Leksell® SurgiPlan with AtlasSpace™
b. Classification Name:	Stereotaxic Instrument 21 CFR 882.4560

17.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Elekta Instruments, AB	Leksell® SurgiPlan	K943468	01/20/1995
Radionics, Inc.	AtlasPlan	K980584	05/18/1998

17.4 DEVICE DESCRIPTION

The Leksell® SurgiPlan with AtlasSpace is intended for use in planning invasive intra-cranial stereotactic procedures. The Leksell SurgiPlan was cleared for commercial distribution under K943468 on January 20, 1995. The purpose of this special premarket 510(k) notification is to describe the addition of the AtlasSpace software module. The AtlasSpace module is a second generation computerized brain atlas, ased on three orthogonal series of the Schaltenbrand-Wahren atlas. The SurgiPlan System has not changed in its functionality or its indications for use. As a result of the addition of the AtlasSpace, the SurgiPlan software and instruction manuals have been updated.

17.5 SUBSTANTIAL EQUIVALENCE

The Leksell® SurgiPlan with AtlasSpace™ is substantially equivalent to the current version of the Leksell® SurgiPlan and the Radionics AtlasPlan™

The fundamental technical characteristics of the Leksell SurgiPlan with AtlasSpace 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 brain atlas software module is equivalent to the brain atlas found in the Radionics AtlasPlan predicate device.

17.6 INDICATIONS FOR USE

The Leksell® SurgiPlan with AtlasSpace is intended for use in planning invasive intra-cranial stereotactic surgical procedures.

17.7 TECHNOLOGICAL CHARACTERISTICS

Modifications have been made to the Leksell® SurgiPlan to add the AtlasSpace software module. The SurgiPlan software program has been enhanced to include a brain atlas that relates the precise anatomy of a patient to a functional or

anatomical map of the brain. AtlasSpace overlays the atlas contours directly on the patient's anatomical images and matches the data in three dimensions using the 3-D Talairach proportional grid. Comparison of the technological characteristics to those of the predicate devices has been provided in this submission.

17.8 PERFORMANCE DATA

Performance testing was conducted on the Leksell SurgiPlan with AtlasSpace based on product specifications and hazard effects determined from the risk analysis. All results of testingand software evaluation were found to be acceptable. The Leksell® SurgiPlan with AtlasSpace performed as intended.

17.9 510(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

DEC 0 6 2001

Elekta Instrument AB
Ms. Carol Patterson
c/o Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, California 92630

Re: K013861
Trade Name: Leksell Surgiplan with Atlasspace™ Accessory
Regulation Number: 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: November 19, 2001
Received: November 21, 2001

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Susan Walker, MD

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

Enclosure

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA K013861

Device Name: Leksell® SurgiPlan with AtlasSpace™

Indications for Use: The Leksell® SurgiPlan with AtlasSpace™ is intended for use in planning invasive intra-cranial stereotactic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-
Division of Ge Restorative
and Neurologic vices

510(k) Number K013861

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)