JUL 20 1999

K991636

SECTION 16: 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.

16.1 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:	May 7, 1999

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Elekta Stereotactic Guide Accessory to the Leksell Image Guidance Surgical System
b. Classification Name:	Stereotaxic Instrument 21 CFR 882.4560

16.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Ohio Medical	Mayfield-ACCISS Workstation	K955397	04/30/96
Ad-Tech	DAP II Biopsy Guide	K830999	07/12/83
Elekta, AB	Leksell Stereotactic System	K972324	03/02/98

16.4 DEVICE DESCRIPTION

The Elekta Stereotactic Guide is an accessory to the Leksell Image Guidance Surgical (LIGS) System. The device consists of a base ring, targeting swivel with instrument channel, and locking ring. The guide and the LIGS are used for guidance and stereotactic instrument positioning during open cranial procedures and surgeries normally performed with traditional stereotactic apparatus. Once the target and entry point is determined during the presurgical planning phase, the craniotomy is made and the Elekta Stereotactic Guide is screwed into the patient's skull at the point of entry. The LIGS probe is placed into the guide and the orientation toward the target is determined using the intra-operative images. The guide is then locked into place and classic stereotactic instruments may then be placed into the channel of the guide for the surgical procedure.

16.5 SUBSTANTIAL EQUIVALENCE

The Elekta Stereotactic Guide, as an Accessory to the Leksell Image Guidance Surgical System, is substantially equivalent to Ohio Medical Instruments Mayfield-ACCISS Workstation, Ad-Tech's DAP II Biopsy Guide and Elekta Instruments' Leksell Stereotactic System.

The fundamental technical characteristics of the Elekta Stereotactic Guide are similar to those of the predicate devices. The design of guide and affixation to the patient is equivalent to the Ad-Tech predicate device. The materials used in the Elekta Stereotactic Guide is equivalent to those used in all three predicate devices. The image guidance capabilities are equivalent to that of the Ohio Medical Instruments predicate device.

The Indications for Use for the Elekta Stereotactic Guide is equivalent to the

K991636

predicate devices in terms of precise stereotactic instrument positioning and image guidance capabilities.

16.6 INTENDED USE

The Elekta Stereotactic Guide is indicated for the guidance and stereotactic instrument positioning in open cranial procedures and surgeries normally performed with traditional stereotactic apparatus.

16.7 TECHNOLOGICAL CHARACTERISTICS

The Elekta Stereotactic Guide is affixed to the patient's cranium. The device consists of a base ring, targeting swivel with instrument channel and locking ring. The base ring provides a rigid fixation for the locking ring and targeting swivel. The instrument channel can accommodate Elekta stereotactic instruments and an Leksell Image Guidance Surgical System probe. A navigational probe is used for determination of the orientation of the target using the intra-operative images of the LIGS system. The guide is locked into place when the correct orientation is obtained. A stop is attached to the stereotactic instrument prior to insertion into the channel. Comparison of the technological characteristics to those of the predicate devices has been provided in this submission.

16.8 PERFORMANCE DATA

The Elekta Stereotactic Guide has been evaluated for performance characteristics using a mechanical accuracy study and a clinical evaluation. Mechanical accuracy was performed on a phantom model with biopsy needle measurements and compared to stereotactic frames. A clinical evaluation of 31 procedures, using the Elekta Stereotactic Guide as an accessory to the Leksell Image

Guidance Surgical System was documented. Both studies show that the Elekta Stereotactic Guide performs as intended.

16.9 510(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

JUL 20 1999

Elekta Instruments, AB
c/o Ms. Carol Patterson
Patterson Consulting Group, Inc.
18140 Smokesignal Drive
San Diego, California 92127

Re: K991636
Trade Name: Elekta Stereotactic Guide
Regulatory Class: II
Product Code: HAW
Dated: May 7, 1999
Received: May 12, 1999

Dear Ms. Patterson:

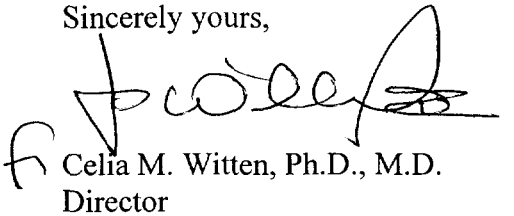
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K991636

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Elekta Stereotactic Guide
Accessory to the Leksell® Image Guidance Surgical System

Indications for Use: The Elekta Stereotactic Guide is indicated for use in guidance and stereotactic instrument positioning in open cranial procedures and surgeries normally performed with traditional stereotactic apparatus.

(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 K991636

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