ELEKTA INSTRUMENT AB

Dokumentnamn/*Name of document*
Special 510(k)

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Anders Skoglund	--	--
Avser/*Regarding*		Directory
Leksell SurgiPlan®		

K080250

Section 4- 510(k) Summary

MAY 13 2008

As Required by 21 CFR 807.87(k)510 (k) Summary

1. *Subscribers Name & Address*

Elekta Instrument AB
Kungstensgatan 18, P.O. Box 7593
SE-103 93 Stockholm, Sweden
Tel: (011) 46 8 587 254 00
Fax: (011) 46 8 587 255 00
Contact Person for this submission: Mr Anders Skoglund
Official Correspondent: Mr Peter Löwendahl

2. *Trade Name*

Leksell SurgiPlan®

3. *Device Classification*

Common Name	Product Code	Class	Regulation Number
Stereotaxic instrument	HAW	II	21 CFR 882.4560

4. *Predicate Device Identification*

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell SurgiPlan®	K033340

5. *Other relevant submissions*

Devices	510(k) #
Leksell SurgiPlan®	K013861
Leksell Stereotactic System®	K031980

1/2

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6. ***Device Description*** (for detailed description see Section "Device Description")

Leksell SurgiPlan® is an advanced image-based neurosurgical planning software, specifically designed for Leksell Stereotactic System®.

7. ***Intended Use***

Leksell SurgiPlan® is intended for use in planning invasive intracranial stereotactic surgical procedures.

8 ***Substantial Equivalence***

The functionality for the Leksell SurgiPlan® is equivalent to its predicate device the Leksell SurgiPlan® (K033340) in safety and effectiveness. The fundamental technical characteristics are the same to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Elekta Instrument AB
% Mr. Anders Skoglund
Regulatory Affairs
P.O. Box 7593
SE-103 93 Stockholm, Sweden

Re: K080250
Trade/Device Name: Leksell SurgiPlan®
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 24, 2008
Received: April 28, 2008

Dear Mr. Skoglund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 7- Indications for Use Statement

510(k) Number	To be defined K080250
Device Name	Leksell SurgiPlan®
Indications for Use	Leksell SurgiPlan® is intended for use in planning invasive intra-cranial stereotactic surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick RP Dyd for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080250