ELEKTA INSTRUMENT AB

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

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Anders Skoglund	--	--
Avser/*Regarding*		Directory
Leksell Stereotactic System® with Reusable Fixation Screws		

MAY - 1 2009

Section 4- 510(k) Summary

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 Stereotactic System® with Reusable Fixation Screws

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 Stereotactic System®	K031999

5. *Other relevant submissions*

Devices	510(k) #
Leksell Stereotactic System®	K031980
Leksell Steretocatic System®	K972324

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

The Reusable Fixation Screws are a part of the Leksell Stereotactic System® and are used to affix the Leksell® Coordinate Frame G firmly to the patient's skull with minimal inconvenience to the patient.

7. ***Intended Use***

The Leksell Stereotactic System® with Reusable Fixation Screws is a system intended for localization and diagnosis of intracranial disorders and their surgical treatment, including radiotherapy and stereotactic radiaton therapy.

8 ***Substantial Equivalence***

The functionality for the Leksell Stereotactic System® with Reusable Fixation Screws is equivalent to its predicate device the Leksell Stereotactic System® (K031999) in safety and effectiveness. The fundamental technical characteristics are the same to those of the predicate device and are listed on the comparison charts provided in this 510 k submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY - 1 2009

Re: K080355
Trade/Device Name: Leksell Stereotactic System® with Reusable fixation Screws
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 27, 2009
Received: April 29, 2009

Dear Mr. Skoglung:

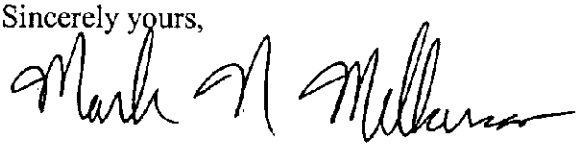
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
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
Device Name	Leksell Stereotactic System® with Reusable Fixation Screws
Indications for Use	The Leksell Stereotactic System® with Reusable Fixation Screws is a system intended for localization and diagnosis of intracranial disorders and their surgical treatment, including radiotherapy and stereotactic radiaton therapy

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

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

510(k) Number K080355