SEP 2 2 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
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Official Correspondent: Mr Anders Skoglund

2. *Trade Name*

Leksell Gamma Knife Perfexion™ with Extend™ Frame System

3. *Device Classification*

Common Name	Product Code	Class	Regulation Number
Radionuclide radiation therapy system.	IWB	II	21 CFR 892.5750

4. *Predicate Device Identification*

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell Gamma Knife Perfexion™	K063512
Headfix	K030439

5. *Other relevant submissions*

Devices	510(k) #
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6. *Device Description* (for detailed description see Section "Device Description")

The Extend™ system is an extension to Leksell Gamma Knife Perfexion™. It consists of a patient fixation system and new software functions in the system application.

The patient fixation system is used to provide target localization and fixation of the patient's head at prescribed geometric coordinates.

7. *Intended Use*

Leksell Gamma Knife Perfexion™ with Extend™ Frame System is a teletherapy device intended for stereotactic irradiation of head structures.

8 *Substantial Equivalence*

The functionality for the Leksell Gamma Knife Perfexion™ with Extend™ Frame System is equivalent to its predicate device the Leksell Gamma Knife Perfexion™ (K063512) and Headfix(K030439) 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 2 2 2009

Mr. Anders Skoglund
Director Regulatory Affairs
Elekta Instrument AB
Kungstensgatan 18 P.O. Box 7593
STOCKHOLM SWEDEN SE-103 93

Re: K092083
Trade/Device Name: Leksell Gamma Knife Perfexion™ with Extend™ Frame System
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: July 7, 2009
Received: July 9, 2009

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 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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 Gamma Knife Perfexion™ with Extend™ Frame System		--

Section 7- Indications for Use Statement

510(k) Number	~~To be defined~~ K092083
Device Name	Leksell Gamma Knife Perfexion™ with Extend™ Frame System
Indications for Use	Leksell Gamma Knife Perfexion™ with Extend™ Frame System is a teletherapy device intended for stereotactic irradiation of head structures.

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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092083