K063512

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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* Leksell Gamma Knife® PERFEXION ™		Directory

Section 4- 510(k) Summary

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

MAR 0 5 2007

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 Gamma Knife® PERFEXION ™

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 ™	K061941

5. *Other relevant submissions*

Devices	510(k) #
Leksell Steretocatic System	K972324
Leksell GammaPlan® PFX	K061540

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

Leksell Gamma Knife® PERFEXION ™ is a radiosurgery system for use in the stereotactic irradiation of intra-cranial structures. Surgery is achieved by delivering a prescribed dose as one or more shots of ionizing radiation to the exact site of the target.

The system consists basically of the radiation unit with patient positioning system and the operator console (with control panel and system computer).

7. *Intended Use*

Leksell Gamma Knife® PERFEXION ™ is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g. metastatic tumors.

8 *Substantial Equivalence*

The functionality for the Leksell Gamma Knife® PERFEXION ™ is equivalent to its predicate device the Leksell Gamma Knife® PERFEXION ™ (K061941) 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.

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

MAR 0 5 2007

Re: K063512
Trade/Device Name: Leksell Gamma Knife® PERFEXION™ System
Regulation Number: 21 CFR §892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: February 15, 2007
Received: February 20, 2007

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 (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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 7- Indications for Use Statement

510(k) Number	K063512
Device Name	Leksell Gamma Knife® PERFEXION ™
Indications for Use	Leksell Gamma Knife® PERFEXION ™ is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g. metastatic tumors.

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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063512