ELEKTA INSTRUMENT AB

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

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Viveka Wretman	--	–
Avser/*Regarding*		Directory
Leksell GammaPlan®		

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: Mrs Viveka Wretman
Official Correspondent: Mr Anders Skoglund

2. *Trade Name*

Leksell GammaPlan®

3. *Device Classification*

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

4. *Predicate Device Identification*

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell GammaPlan®	K090972
XiO RTP	K092132

5. *Other relevant submissions*

Devices	510(k) #
NA	

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

Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with the Leksell Gamma Knife®. Leksell Gamma Plan® is intended to be used for planning the dosimetry of treatments, in stereotactic radiosurgery and stereotactic radiotherapy.

7. ***Intended Use***

Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with Leksell Gamma Knife®.

8 ***Substantial Equivalence***

The functionality for Leksell GammaPlan® is equivalent to its predicate devices Leksell GammaPlan® (K090972) and XiO RTP System (K092132) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate devices.

Elekta Instrument AB, P.O. Box 7593, SE-103 93 Stockholm, Sweden Tel +46 8 587 254 00 Fax +46 8 587 255 00

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

Mr. Bo Nilsson
Director Quality & Regulatory Affairs
Elekta Instrument AB, Box 7593
SE-103 93 Stockholm
SWEDEN

DEC 2 1 2010

Re: K103093
Trade/Device Name: Leksell GammaPlan®
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 30, 2010
Received: December 2, 2010

Dear Mr. Nilsson:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

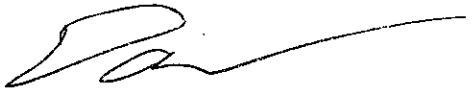
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

DEC 2 1 2010

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Leksell GammaPlan®		

Section 7- Indications for Use Statement

510(k) Number	To be defined
Device Name	Leksell GammaPlan®
Indications for Use	Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with Leksell Gamma Knife®.

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)~~ (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103093