Utfärdare/Issuer	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition
Anders Skoglund	-	1
Avser/Regarding Leksell GammaPlan 4C with MultiView		Directory

K042269

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 GammaPlan 4C with MultiView

3. Device Classification

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

4. Regulatory History (Unmodified Predicate Device)

Devices	510(k) #
Leksell GammaPlan	K973441

5. Other relevant submissions

Devices	510(k) #
Leksell Surgiplan with Atlaspace	K013861
Leksell Surgiplan with Imagemerge	K033340

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

The Leksell GammaPlan 4C with MultiView adds support for frameless images by means of co-registration of image series. This simplifies stereotactic radiosurgery procedures as only one image series needs to be acquired with the Leksell stereotactic frame. Leksell GammaPlan 4C with MultiView also adds support for brain altas structures and visualization of color mapped PET images for use in preoperative planning.

7. Intended Use

The Leksell GammaPlan 4C with MultiView is a computer-based dose planning system specifically designed for use with the Leksell Gamma Knife®. The Leksell GammaPlan 4C with MultiView is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgey and stereotactic radio therapy. It processes the inputs from the healt care professionals such that the desired radiation dose is provided by the Leksell Gamma Knife® to a precisely defined target area within the cranium.

8 Substantial Equivalence

The functionality for the Leksell GammaPlan 4C with MultiView is equivalent to its predicate device Leksell GammaPlan (K973441) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. Peter Löwendahl
Quality and Regulatory Affairs Manager
Elekta Instrument AB
P.O. Box 7593
SE-103 93 Stockholm
SWEDEN

Re: K042269
Trade/Device Name: Leksell GammaPlan 4C with MultiView
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: August 20, 2004
Received: August 23, 2004

Dear Mr. Löwendahl:

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

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Utfärdare/Issuer	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition
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Avser/Regarding		Directory
Leksell GammaPlan 4C with MultiView		

Section 7- Indications for Use Statement

510(k) Number: To be defined K042269

Device Name: Leksell GammaPlan 4C with MultiView

Indications for Use: The Leksell GammaPlan 4C with MultiView is a computer-based dose planning system specifically designed for use with the Leksell Gamma Knife®. The Leksell GammaPlan 4C with MultiView is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgey and stereotactic radio therapy. It processes the inputs from the healt care professionals such that the desired radiation dose is provided by the Leksell Gamma Knife® to a precisely defined target area within the cranium.

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)

David A. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042269