ELEKTA

RECEIVED
AUG 25 2006
BY:

Ms. Cynthia Sanders
Program Manager
Radioactive Materials Program
Georgia Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta GA 30354

August 22, 2006

Dear Ms. Sanders,

Elekta, Inc. has now received FDA 510(k) approval for the Leksell Gamma Knife® PERFEXION™. We are very pleased to have obtained a FDA clearance in a shorter than expected timeframe. Attached is the approval for your review in conjunction with the sealed source and device application that was submitted on May 31, 2006.

Should you have any questions or require additional information, please do not hesitate to contact me.

Best regards,
ELEKTA, INC.

Melissa Chapman
Regulatory Affairs Specialist

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 21 2006

Mr. Peter Löwendahl
Director Group Regulatory Affairs
Elekta Instrument AB
P.O. Box 7593
SE-103 93 Stockholm
SWEDEN

Re: K061941
Trade/Device Name: Leksell Gamma Knife® PERFEXION™
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: July 6, 2006
Received: July 10, 2006

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 (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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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,

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

ELEKTA INSTRUMENT AB

Dokumentnamn/Name of document: Traditional 510(k) 79

Utfärdare/Issuer	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition
Anders Skoglund	--	--
Avser/Regarding: Leksell Gamma Knife® PERFEXION ™		Directory: --

Section 7- Indications for Use Statement

510(k) Number	To be defined K061941
Device Name	Leksell Gamma Knife® PERFEXION ™
Indications for Use	Leksell Gamma Knife® PERFEXION ™ is a teletherapy device intended for use in the stereotactic irradiation of intra-cranial structures.

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 B. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061941