DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 3, 2015

Elekta Instrument AB
% Ms. Matilda Forsberg
Regulatory Affairs Engineer
Kungstensgatan 18
Stockholm, 10393
SWEDEN

Re: K151666
Trade/Device Name: Leksell GammaPlan
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: June 14, 2015
Received: June 19, 2015

Dear Ms. Forsberg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151666

Device Name
Leksell GammaPlan®

Indications for Use *(Describe)*
Leksell GammaPlan® is a computer-based system designed for Leksell Gamma Knife® treatment planning.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

As Required by 21 CFR 807.92(c) 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
Official Correspondent: Ms Louise Wachtmeister

Date summary prepared: 2015-06-10

2. Trade Name

Leksell GammaPlan®

3. Device Classification

Common Name	Product Code	Class	Regulation Number
Leksell GammaPlan®	MUJ	II	21 CFR 892.5050

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell GammaPlan®	K103093

5. Other relevant submissions

Devices	510(k) #
Leksell GammaPlan®	K090972

6. Device Description

Leksell GammaPlan® is designed for use with the Leksell Gamma Knife and is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. It processes the inputs of health care professionals (e.g. neurosurgeons, radiation therapists, radiation physicists) such that the desired radiation dose is delivered by the Leksell Gamma Knife to a precisely defined volume.

7. Summary of Clinical Testing

Clinical testing on patients was not required to demonstrate substantial equivalence or safety and effectiveness of the device.

8. Summary of Non Clinical and Performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against requirement specification. Regression and re-test of unchanged functionalities in the developed system was done to ensure that the new and updated functionalities did not introduce any undesirable effects.

Design and usability validation of the system has been performed by competent and professionally qualified personnel to ensure that the product fulfils the intended use and user needs. The design and usability validation was also made to ensure that the risk control measures associated with functions related to safety (FRS) for the new functionality was effective.

Results from verification and validation testing demonstrate that conformance to applicable technical requirement specification and user needs have been met and safety & effectiveness have been achieved.

9. Intended Use

Leksell GammaPlan® is a computer-based system designed for Leksell Gamma Knife® treatment planning.

10. Technological Characteristics

Leksell GammaPlan® is designed for use with the Leksell Gamma Knife and is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. The fundamental functionality and technical characteristics of the device are similar to those of the predicate device K103093.

11. Substantial Equivalence

The functionality for Leksell GammaPlan® is equivalent to its predicate device Leksell GammaPlan® (K103093) in safety and effectiveness. The following workflows have been added to the new version:

- Stereotactic reference can be defined from stand-alone Cone Beam CT (CBCT)
- Mask fixation support with automatic patient position correction from CBCT
- Guided treatment delivery evaluation after CBCT with review of delivery dose

The indication for use is the same as its predicate device and the fundamental technical characteristics are similar.