February 9, 2018

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

Re: K173791
Trade/Device Name: Leksell GammaPlan®
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB, MUJ
Dated: December 12, 2017
Received: December 14, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173791

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 4- 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: Pia Lindberg

Date summary prepared: 2017-12-01

2. Trade Name

Leksell GammaPlan®

3. Common Name

Treatment planning system

4. Device Classification

Trade Name	Product Code	Regulation Number	Device Class	Classification Panel
Leksell GammaPlan®	IWB, MUJ	21 CFR 892.5750	II	Radiology

5. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell GammaPlan®	K151666

6. Other relevant submissions

Device	510(k) #
Leksell Gamma Knife Icon	K160440
Leksell Gamma Knife Perfexion	K151159

7. 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.

8. Summary of clinical testing

Clinical testing on patients was not required to demonstrate substantial equivalence to the predicate device.

9. 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.

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 that the system is confident and stable.

10. Intended Use

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

11. 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 the same as the predicate device, K151666.

12. Substantial Equivalence

The Leksell GammaPlan® has the following similarities to the previous cleared Leksell GammaPlan® (K151666):

- Same indication for use
- Use the same operating principle
- Build on the same software platform

Compared to the previously cleared Leksell GammaPlan (K151666) this new version includes support for both Leksell Gamma Knife® Icon and Leksell Gamma Knife Perfexion. In addition, the following changes have been made:

- **Support for non-square images for the purpose of pre-planning and follow up.**

It is now possible to import and co-register non-square images for the purpose of pre-planning and follow-up

- **Volumetric margin expansion tool.**

A new margin tool that allows for performing volumetric expansion of delineated volumes has been added.

- **DICOM import improvements**
    - The DICOM import dialog has an improved layout that includes image preview and easier navigation of DICOM attributes.
    - For easier identification of image series, the series description is now both displayed upon selection, and assigned as the default name for imported image series upon DICOM import.
    - DICOM import from USB storage device has been added.
    - Possible to view DICOM attributes for an already imported image series

- **New Operating System**
    - Upgrade to CentOS 7.1 with from CentOS 5.8

Summary:

The fundamental technical characteristics and indication for use is the same as the previously cleared device, only new support is added. The conclusion is that Leksell GammaPlan® is substantial equivalent to its predicate device.