Elekta Solutions AB
% Simon Sjohage
Regulatory Affairs Engineer
Kungstensgatan 18 Box 7593
Stockholm, Stockholm SE-10393
SWEDEN

February 8, 2024

Re: K232854
Trade/Device Name: Leksell GammaPlan® (LGP)
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system.
Regulatory Class: Class II
Product Code: IWB, MUJ
Dated: September 13, 2023
Received: September 15, 2023

Dear Simon Sjohage:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232854

Device Name

Leksell GammaPlan® (LGP)

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.

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510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

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Phone: +46 (8) 58725637

Establishment Registration #: 3015232217

510(k) Number: K232854

Date Prepared: 13 September 2023

II. DEVICE

Trade Name:	Leksell GammaPlan® (LGP)
Release Version:	Release 11.4
Product Classification:	Class II
Common Name:	Radionuclide RT Treatment planning system
Regulation Number:	21 CFR § 892.5750
Regulation Description:	Radionuclide radiation therapy system
Product Code:	IWB, MUJ

III. PREDICATE DEVICE

Leksell GammaPlan® (K173791)

IV. INTENDED USE / INDICATIONS FOR USE

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

V. DEVICE DESCRIPTION

Leksell GammaPlan® is a powerful, computer-based treatment planning system specifically designed for the simulation and planning of stereotactic Leksell Gamma Knife® radiosurgery based on tomographic and projectional images.

The basis of treatment planning is the acquisition and processing of digital images by a computer workstation running the treatment planning application software. The program is capable of handling a range of different imaging modalities. Images from tomographic sources such as Computer Tomography (CT), Magnetic Resonance (MR) and Positron Emission Tomography (PET) scanners can be used as well as projectional images from angiograms (AI). This allows the direct comparison between vascular structures in projectional images and tissue structures in CT and MR.

Digital images can be imported into the system via the computer network.

The treatment planning application has the ability to plan a patient's treatment protocol based on a single target or multiple targets.

The basic elements of treatment planning are:

- defining the cranial target or targets
- devising the configuration of the collimators to be used during treatment
- determining the parameters of the radiation shots to be delivered by Leksell Gamma Knife®.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The major changes in this release, as compared to the previously cleared version, are primarily the ability to compare alternative plans simultaneously and the possibility to import DICOM RT Doses from external DICOM compliant systems.
The fundamental technical characteristics and the principles of operation of the subject device Leksell GammaPlan version 11.4 have not changed and are substantially equivalent to its predicate device Leksell GammaPlan K173791.

VII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Development, verification, and validation activities for the modified SaMD were carried out in accordance with design controls as required by FDA's Quality System Regulation (21 CFR §820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 Risk Management requirements, and IEC 62304 requirements for software life-cycle processes. Non-clinical testing was performed to evaluate device performance and functionality in accordance with design and risk management requirements at subsystem, integration and system levels including interoperability.

Documentation of software development and verification testing activities for LGP is maintained in accordance with FDA's "*Guidance for the Content of Premarket Submissions for Device Software Functions,*" June 2023, for an Enhanced Documentation Device (Class C per IEC 62304).

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 specifications.

Formal design and usability validation has been performed on a clinically equivalent device 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 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.

VIII. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that the Leksell GammaPlan is as safe and effective and performs as well as the predicate device.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

Leksell GammaPlan v11.4 is substantially equivalent (SE) to the predicate device, Leksell GammaPlan (K173791). The intended use and indications for use are identical to the predicate device and the principles of operation remain unchanged.

The technological characteristics are substantially equivalent to the predicate device; enhancements to existing functionality do not affect the fundamental scientific technology or raise different questions of safety or effectiveness of the device. The device safety and performance have been addressed by non-clinical testing in conformance with predetermined performance criteria, FDA guidance, and recognized consensus standards.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that LGP v11.4 meets the established safety and performance criteria and is substantially equivalent to the predicate device.