July 2, 2025

Elekta Solutions AB
Simon Sjöhage
Senior Regulatory Affairs Engineer
Hagaplan 4
Stockholm, 113 68
Sweden

Re: K250391
Trade/Device Name: Leksell Gamma Knife® (Elekta Esprit); Leksell Gamma Knife® (Icon™); Leksell Gamma Knife® (Perfexion™)
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide Radiation Therapy System
Regulatory Class: Class II
Product Code: IWB
Dated: February 12, 2025
Received: February 12, 2025

Dear Simon Sjöhage:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250391

Device Name

Leksell Gamma Knife® (Elekta Esprit);
Leksell Gamma Knife® (Icon™);
Leksell Gamma Knife® (Perfexion™)

Indications for Use *(Describe)*

Leksell Gamma Knife® is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g.

- Metastatic tumors
- Recurrent glioblastomas
- Trigeminal neuralgia
- Medically refractory essential tremor
- Orbital tumors
- Ocular tumors
- Optic nerve tumors
- Benign diseases (such as meningiomas, vestibular schwannomas, post-surgical pituitary adenomas, craniopharyngioma, hemangioblastomas, schwannomas, arteriovenous malformations, cavernous malformations, chordomas, glomus tumors, hemangiomas)
- Skull base tumors
- Head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, oropharynx, nasopharynx, sinonasal, salivary gland)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors)
- Refractory mesial temporal lobe epilepsy in adults
- Refractory epilepsy associated with structural changes such as hamartomas, cerebral cavernous malformations, and arteriovenous malformations (adult and pediatric)

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.

Traditional 510(k) Summary (21 CFR § 807.92)

I. Submitter

Address	Elekta Solutions AB
	Hagaplan 4
	113 68 Stockholm
	Sweden
Contact	Simon Sjöhage
	Senior Regulatory Affairs Engineer
	+46707994829
	Simon.Sjohage@elekta.com

510(k) Number	K250391
Date Prepared	2025-06-05

II. Device

Trade Name	Leksell Gamma Knife® – Elekta Esprit
	Leksell Gamma Knife® Icon™
	Leksell Gamma Knife® Perfexion™
Product Classification	Class II
Common Name	Radionuclide radiation therapy system
Regulation Number	892.5750
Product Code	IWB

III. Predicate Device

Predicate #	K222047
Predicate Trade Name	Leksell Gamma Knife® (Elekta Esprit, Icon™, and Perfexion™)
Predicate Product Code	IWB

IV. Device Description Summary

Leksell Gamma Knife® (available models Elekta Esprit, Icon™, and Perfexion™) is a radiosurgery system for use in the stereotactic irradiation of head structures. Surgery is achieved by delivering a prescribed dose as one or more shots of ionizing radiation to the exact site of the target.

Elekta Solutions AB | Box 7593 | SE-103 93 Stockholm | Sweden
Tel: +46 8 587 254 00 | Fax: +46 8 587 255 00 | www.elekta.com | Reg No. 559157-5286

V. Intended Use/ Indications for Use

Leksell Gamma Knife® is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g.

- Metastatic tumors
- Recurrent glioblastomas
- Trigeminal neuralgia
- Medically refractory essential tremor
- Orbital tumors
- Ocular tumors
- Optic nerve tumors
- Benign diseases (such as meningiomas, vestibular schwannomas, post-surgical pituitary adenomas, craniopharyngioma, hemangioblastomas, schwannomas, arteriovenous malformations, cavernous malformations, chordomas, glomus tumors, hemangiomas)
- Skull base tumors
- Head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, oropharynx, nasopharynx, sinonasal, salivary gland)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors)
- Refractory mesial temporal lobe epilepsy in adults
- Refractory epilepsy associated with structural changes such as hamartomas, cerebral cavernous malformations, and arteriovenous malformations (adult and pediatric)

VI. Indications for Use Comparison

The differences are not critical to the intended use and the differences do not affect the safety and effectiveness of the device when used as labeled as the device has the identical intended use (teletherapy to brain structures) as the existing device. A comparison is provided in the below table:

#	Predicate device (K222047)	Subject device	Comparison discussion
Intended use	*Leksell Gamma Knife® is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g.*	*Leksell Gamma Knife® is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g.*	Identical
E.g. Indications for use	- *Metastatic tumors* - *Recurrent glioblastomas* - *Trigeminal neuralgia* - *Medically refractory essential tremor* - *Orbital tumors* - *Ocular tumors* - *Optic nerve tumors* - *Benign diseases (such as meningiomas, vestibular schwannomas, post-surgical pituitary adenomas, craniopharyngioma, hemangioblastomas, schwannomas, arteriovenous malformations, cavernous malformations, chordomas, glomus tumors, hemangiomas)* - *Skull base tumors* - *Head and neck tumors (such as*	- *Metastatic tumors* - *Recurrent glioblastomas* - *Trigeminal neuralgia* - *Medically refractory essential tremor* - *Orbital tumors* - *Ocular tumors* - *Optic nerve tumors* - *Benign diseases (such as meningiomas, vestibular schwannomas, post-surgical pituitary adenomas, craniopharyngioma, hemangioblastomas, schwannomas, arteriovenous malformations, cavernous malformations, chordomas, glomus tumors, hemangiomas)* - *Skull base tumors* - *Head and neck tumors (such as*	Substantially equivalent. The general purpose of the device and its functions is not affected. The new indication (Refractory mesial temporal lobe epilepsy in adults) falls within the intended use of the predicate device (stereotactic irradiation of head structures). For certain diseases that can result in epilepsy, such as hamartomas, cerebral cavernous malformations, and arteriovenous malformations, radiation treatment is already on-label for both the pediatric and adult population. Clinical performance of the Leksell Gamma Knife for all indications (including this new and additional indication) demonstrates a favorable benefit-risk profile.

	unknown primary of the head and neck, oral cavity, hypopharynx, oropharynx, nasopharynx, sinonasal, salivary gland) - *Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors)*	*unknown primary of the head and neck, oral cavity, hypopharynx, oropharynx, nasopharynx, sinonasal, salivary gland)* - *Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors)* - ***Refractory mesial temporal lobe epilepsy in adults*** - ***Refractory epilepsy associated with structural changes such as hamartomas, cerebral cavernous malformations, and arteriovenous malformations (adult and pediatric)***	

VII. Technological Comparison

Leksell Gamma Knife® (available models Elekta Esprit, Icon™, and Perfexion™) is a radiosurgery system for use in the stereotactic irradiation of intra-cranial structures. Surgery is achieved by delivering a prescribed dose as one or more shots of ionizing radiation to the exact site of the target.

The major changes of technological characteristics of the Leksell Gamma Knife® (subject device), as compared to the predicate device Leksell Gamma Knife® (K222047) are primarily replacement of obsolete hardware components.

Feature	Predicate Device (K222047)	Subject Device	Comparison Discussion
# of radiation sources	192	192	Identical
Operating System	Windows 10	Windows 10	Identical
LGK treatment control system	Control System SW 11.5	Control System SW 11.6	Version 11.6 enables the new hardware released with this version. The ECU hosting the control system is replaced with a new ECU with a modified design. The change in design required a new risk control to be added to ensure the same level of safety as predicate

			device and thus ensuring substantial equivalence.
User Interface	Model Esprit: Functional KeyPad (FKP) & Isolation and Patient Surveillance Unit (IPSU) Model Icon and Perfexion : Operator Control (OPC)	Model Esprit: Functional KeyPad (FKP) & Isolation and Patient Surveillance Unit (IPSU) Model Icon and Perfexion : Operator Control (OPC)	Identical
Patient Surveillance System (PSS)	Model Esprit: Digital PSS Camera Model Icon and Perfexion: Analog Video Camera	Model Esprit: Digital PSS Camera Model Icon and Perfexion: Analog Video Camera	Identical
Fixation	Model Esprit and Icon: Frame (G-frame, Vantage), & and Mask Model Perfexion: Frame (G-frame)	Model Esprit and Icon: Frame (G-frame, Vantage), & and Mask Model Perfexion: Frame (G-frame)	Identical
Imagin Modality	Model Esprit and Icon: kV X-ray/CBCT Model Perfexion: na	Model Esprit and Icon: kV X-ray/CBCT Model Perfexion: na	The old kV-generator used in the CBCT system is replaced with a new one. The clinical workflow, safety, functionality, and performance is unchanged thus ensuring substantial equivalence.
Patient Movement Detection System	Model Esprit and Icon: High Definition Motion Management System (HDMM) Model Perfexion: na	Model Esprit and Icon: High Definition Motion Management System (HDMM) Model Perfexion: na	The HDMM camera is replaced with a new one. The clinical workflow, safety, functionality, and performance is unchanged thus ensuring substantial equivalence.

The fundamental technical characteristics of the subject device Leksell Gamma Knife® have not changed and are substantially equivalent to its predicate device Leksell Gamma Knife® (K222047)

VIII. Summary of Performance Testing (Non-Clinical)

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new control system and the new hardware against requirement specification.

Regression test of unchanged functionalities in the developed system was done to ensure that new and updated functionalities did not introduce any undesirable effects.

Performance testing, including 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 affected functionality, mainly the user interface of the Control Panel were effective.

In relation to the new indications for use, updated labeling was in scope of usability evaluation according to IEC 62366-1. The result demonstrate that the labeling support the safe and effective use of the device. Update of the ECU, kV-generator, HDMM-camera, or the new control system version did not require usability validation and previous data from the predicate device remain valid.

Verification testing has been done to the following standards to ensure safety of the device:

- IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-2-11, IEC 60601-2-28, IEC 60601-2-68
- IEC 62304
- IECO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-18, ISO 10993-23
- IEC 62366-1

Results from verification and validation testing demonstrate that conformance to applicable technical requirement specification, user needs have been met and that the device functions as intended.

Biocompatibility testing has been performed to ensure that all materials are biocompatible in relation to the use of the device.

IX. Summary of Performance Testing (Clinical)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that the subject device is as safe and effective and performs as well as the predicate devices (K222047).

X. Substantial Equivalence Conclusion

Leksell Gamma Knife® is claimed to be substantially equivalent (SE) to the predicate device Leksell Gamma Knife® (K222047). The intended use is identical and the difference in indications are not critical to the intended use and the principle of operation remain unchanged.

New hardware has been introduced to replace old obsolete components. A new control system software version has been introduced to support and enable the new components. The subject device does not introduce any new clinical requirements or functions.

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

The result of verification and validation as well as conformance to relevant safety standards demonstrate that the Leksell Gamma Knife® meets the established safety and performance criteria and is substantially equivalent to the predicate device.