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

Re: K222047
Trade/Device Name: Leksell Gamma Knife® Perfexion™, Leksell Gamma Knife® Icon™, Leksell Gamma Knife® - Elekta Esprit
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: Class II
Product Code: IWB
Dated: September 27, 2022
Received: September 28, 2022

Dear Helena Skar:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for

Daniel M. Krainak, Ph.D.
Assistant Director
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)*

K222047

Device Name

Leksell Gamma Knife® Icon™, Leksell Gamma Knife® Perfexion™, and Leksell Gamma Knife® – Elekta Esprit

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)

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

Elekta Solutions AB
Kungstensgatan 18 Box 7593
SE-10393 Stockholm, Sweden

Contact: Helena Skar
Regulatory Affairs Engineer

Establishment Registration #: 3015232217
510(k) Number: K222047
Date Prepared: 19 September 2022

II. DEVICE

Trade Name: Leksell Gamma Knife® Perfexion, Leksell Gamma Knife® Icon™, and Leksell Gamma Knife® – Elekta Esprit
Product Classification: Class II
Common Name: Leksell Gamma Knife®
Regulation Number: 21 CFR § 892.5750
Regulation Description: Radionuclide radiation therapy system
Product Code: IWB

III. PREDICATE DEVICE

K173789 – Leksell Gamma Knife Perfexion & Leksell Gamma Knife Icon

IV. 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)

V. DEVICE DESCRIPTION

Leksell Gamma Knife® (available models Icon™, Perfexion™ and Elekta Esprit) 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Leksell Gamma Knife® (available models Icon™, Perfexion™ and Elekta Esprit) 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 new model Leksell Gamma Knife® – Elekta Esprit (subject device), as compared the predicate device Leksell Gamma Knife® (K173789) are primarily update enhancements to the hardware user interface in the operator room, which affected both the hardware and software.

Feature	Perfexion	Icon	Elekta Esprit
# of radiation sources	192		192
Operating system	Windows 10		Windows 10
LGK treatment control system	Control system SW 11.5		Control system SW 11.5
User Interface	Operator Control (OPC)		Functional KeyPad (FKP) & Isolation & Patient Surveillance Unit (IPSU)
Patient Positioning System (PPS)	The patient couch runs on rails installed in the framework with an adjustable mattress and knee support on top. The HDMM IR Camera is attached to the frame.		• New material in the mattress and knee support. • Dampening hinges (soft close) on side protection • New shape, color and material on the HDMM IR camera arm • New shape of the PPS tray assembly
Patient Surveillance System (PSS)	Analog video camera		Digital PSS Camera
Fixation	Frame only (G-frame, Vantage)	Frame (G-frame, Vantage) & Mask	Frame (G-frame, Vantage) & Mask
Imaging Modality	N/A	kV X-rays / CBCT	kV X-rays / CBCT
Patient Movement Detection System	N/A	IFMM	IFMM (Intra fraction motion management system)

The fundamental technical characteristics of the subject device Leksell Gamma Knife® – Elekta Esprit have not changed and are substantially equivalent to its predicate device Leksell Gamma Knife® (K173789).

VII. SUMMARY OF PERFORMACE 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.

Design and usability validation of the system have 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.

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.

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 Gamma Knife – Elekta Esprit is as safe and effective and performs as well as the predicate devices Leksell Gamma Knife Icon and Leksell Gamma Knife Perfexion.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

Leksell Gamma Knife® – Elekta Esprit is claimed to be substantially equivalent (SE) to the predicate device, Leksell Gamma Knife® (K173789). The intended use and indications for use are identical to the predicate devices and the principles of operation remain unchanged.

New hardware has been introduced for the subject device, to enhance the user interface and to provide a modernized model. A new control system software version has been introduced to support the new hardware in the new model Elekta Esprit. Leksell Gamma Knife® – Elekta Esprit does not introduce any new clinical requirements or functions.

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 the Leksell Gamma Knife® – Elekta Esprit meets the established safety and performance criteria and is substantially equivalent to the predicate device.