August 5, 2026

Elekta Solutions AB
Jesper Bruske
Regulatory Affairs Engineer
Hagaplan 4
Stockholm, 113 68
Sweden

Re: K261932
Trade/Device Name: Leksell® Vantage Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 9, 2026
Received: June 9, 2026

Dear Jesper Bruske:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JAIME RABEN -S

Jaime Raben, PhD
Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261932

Please provide the device trade name(s).

Leksell® Vantage Stereotactic System

Please provide your Indications for Use below.

The intended purpose of Leksell® Vantage Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures; for example deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

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

I. Submitter

Address	Elekta Solutions AB
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Contact	Jesper Bruske
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510(k) Number	TBD
Date Prepared	2025-06-09

II. Device

Trade Name	Leksell® Vantage Stereotactic System
Product Classification	Class II
Common Name	Neurological Stereotaxic Instrument
Regulation Number	882.4560
Product Code	HAW

III. Predicate Device

Predicate #	K190887 (Primary Predicate)
	K152558 (Predicate)
Predicate Trade Name	Leksell® Vantage Stereotactic System (Primary Predicate)
	Leksell® Stereotactic System (Predicate)
Predicate Product Code	HAW

IV. Device Description Summary

The Leksell® Vantage Stereotactic System is a medical device used for minimally invasive neurosurgical procedures. It enables coordinate referencing of the brain and fixation of the patient's skull during image acquisition and treatment. The coordinate referencing enables target localization and accurate stereotactic treatment of brain targets; such as aspirations, biopsies, electrode placements, injections of cells & drugs, heamatoma evacuations as well as lesioning using a number of methodologies.

V. Intended Use/ Indications for Use

The intended purpose of the Leksell® Vantage Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures; for example deep brain stimulation, lesioning, biopsies, target injections, aspirations and minimal invasive tumor treatments.

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VI. Indications for Use Comparison

The intended use of the subject device and the primary predicate device (K190887) are the same. The addition of the X-ray accessories and Starburst Adapters does not affect the intended use.
The intended use of X-ray Fiducial Box and X-ray Table Fixations is the same as the predicate device (K152558)

Subject Device	Primary Predicate Device K190887	Predicate Device K152558
The intended purpose of Leksell® Vantage Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.	The Intended Purpose of Leksell® Vantage™ Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.	The Leksell Stereotactic System® with Reusable Fixation Screws is a system intended for localization and diagnosis of intracranial disorders and their surgical treatment, including radiosurgery and stereotactic radiation therapy.

VII. Technological Comparison

The Leksell® Vantage Stereotactic System is a medical device used for minimally invasive neurosurgical procedures. It enables coordinate referencing of the brain and fixation of the patient's skull during image acquisition and treatment. The coordinate referencing enables target localization and accurate stereotactic treatment of brain targets; such as aspirations, biopsies, electrode placements, injections of cells & drugs, heamatoma evacuations as well as lesioning using a number of methodologies.

The major change of the Leksell® Vantage Stereotactic System (subject device), as compared to the primary predicate device Leksell® Vantage Stereotactic System (K190887) is addition of X-ray accessories.

The fundamental technical characteristics of the subject device Leksell® Vantage Stereotactic System have not changed and are substantially equivalent to its predicate device Leksell® Vantage Stereotactic System (K190887). The subject device is also substantially equivalent to predicate device (K152558) regarding usage of X-ray accessories.

Item category description	Item identifier	Subject device	Primary Predicate device K190887	Predicate device K152558
Trade Name	/	Leksell® Vantage Stereotactic System	Leksell® Vantage™ Stereotactic System	Leksell Stereotactic System®
Class	/	Class II	Class II	Class II
Regulation	/	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560
Product Code	/	HAW	HAW	HAW
Description	/	Head Frame and semi-circular arc system used for the coordinate referencing of targets in the brain and the guidance of neurosurgical instruments to these brain targets.	Head Frame and semi-circular arc system used for the coordinate referencing of targets in the brain and the guidance of neurosurgical instruments to these brain targets.	Head Frame and semi-circular arc system used for the coordinate referencing of targets in the brain and the guidance of neurosurgical instruments to these brain targets.
Use Environment	/	Access-controlled Healthcare facilities	Access-controlled Healthcare facilities	Access-controlled Healthcare facilities
Indications for Use / Intended Use	/	The intended purpose of Leksell® Vantage Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.	The Intended Purpose of Leksell® Vantage™ Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.	The Leksell Stereotactic System® with Reusable Fixation Screws is a system intended for localization and diagnosis of intracranial disorders and their surgical treatment, including radiosurgery and stereotactic radiation therapy.
Principles of Use	/	Center of the arc principle using an arc radius of 190 mm. Cartesian coordinates applied to the brain of the patient by the use of a head frame fixated to the skull. • comprises a headframe and arc, • is target centered • uses Cartesian (x,y,z) coordinates to triangulate target position in frame • utilizes fiducial markers that can be registered to a stereotactic brain atlas and/or intracranial image, • provides support and accessories for surgical instruments to the target	Center of the arc principle using an arc radius of 190 mm. Cartesian coordinates applied to the brain of the patient by the use of a head frame fixated to the skull. • comprises a headframe and arc, • is target centered • uses Cartesian (x,y,z) coordinates to triangulate target position in frame • utilizes fiducial markers that can be registered to a stereotactic brain atlas and/or intracranial image, • provides support and accessories for surgical instruments to the target	Center of the arc principle using an arc radius of 190 mm. Cartesian coordinates applied to the brain of the patient by the use of a head frame fixated to the skull. • comprises a headframe and arc, • is target centered • uses Cartesian (x,y,z) coordinates to triangulate target position in frame • utilizes fiducial markers that can be registered to a stereotactic brain atlas and/or intracranial image, • provides support and accessories for surgical instruments to the target,
Technical Features	Coordinate System Fixation	Coordinate System: Leksell Coordinate System using Cartesian coordinates Fixation: Head Frame applied to patient skull with four fixation pins	Coordinate System: Leksell Coordinate System using Cartesian coordinates Fixation: Head Frame applied to patient skull with four fixation pins	Coordinate System: Leksell Coordinate System using Cartesian coordinates Fixation: Head Frame applied to patient skull with four fixation pins.

Technical Features	Fixation pins	Fixation Pins: Single use Fixation Pins and Inserts that secures the Vantage head frame to the patient skull using Leksell Vantage Keys	Fixation Pins: Single use Fixation Pins and Inserts that secures the Vantage head frame to the patient skull using Leksell Vantage Keys	Fixation Pins: Titanium Fixation Pins that secure the Leksell Coordinate Frame G to the patient skull using Instrument Screw Drivers
Imaging modality	/	CT, MR and X-ray	CT and MR	CT, MR and X-ray
Technical Features	X-ray accessories	The X-ray Fiducial box is used during stereotactic X-ray imaging to impose fiducials on images of the patient. The fiducials are used for determining target coordinates during angiography. The X-Ray fiducial box consists of four labeled fiducial plates (RIGHT and LEFT, ANTERIOR and POSTERIOR). The fiducials are made of high-density material to impose markers that are clearly visible on angiograms. X-ray table fixations are provided to prevent motions and keep the patient attached to the table during imaging.	/	The X-Ray Indicator with Markers is an accessory for target localization in stereotactic neurosurgery and radiosurgery. It is used in conjunction with Leksell Coordinate Frame G. The purpose of the indicator is to impose fiducials on X-ray films of the patient. The fiducials are used for target localization X-ray table fixations are provided to prevent motions and keep the patient attached to the table during imaging.
Accuracy	/	Mechanical accuracy 0.9 mm	Mechanical accuracy 0.9 mm	Mechanical accuracy 0.9 mm
Biocompatibility	/	Materials have been assessed based on ISO 10993-1	Materials have been assessed based on ISO 10993-1	Materials have been assessed based on ISO 10993-1
Accessories	/	Neurosurgical Instruments with working length of 190 mm	Neurosurgical Instruments with working length of 190 mm	Neurosurgical Instruments with working length of 190 mm

VIII. Summary of Performance Testing (Non-Clinical)

Verification activities have been performed to demonstrate that the X-ray accessories work as intended according to the system requirements for the Leksell Vantage Stereotactic System and its relevant subsystem requirements and that there is no unforeseen side-effect to the existing product base of Leksell Vantage Stereotactic System resulting in the changes made.

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.

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.

The new X-ray accessories have also been evaluated for biocompatibility.

IX. Summary of Performance Testing (Clinical)

No animal or clinical tests were performed to establish substantial equivalence with the predicate devices. The performance data demonstrate that the subject device is as safe and effective and performs as well as the predicate devices (K190887 and K152558).

X. Substantial Equivalence Conclusion

The intended use, the basic functionality, and the fundamental technological features of the Leksell Vantage Stereotactic System did not change.

The subject device remains as safe and effective as the primary predicate device (K190877) and predicate device (K152558).

The subject device does not raise different questions of safety and effectiveness than the predicate devices and safety and effectiveness is demonstrated with the same methods (FDA guidance and recognized consensus standards) and with the same results of the predicate devices. This shows that the subject device is substantially equivalent to the primary predicate device (K190877) in intended use, principles of operation, technological characteristics, performance, and labelling. Also, the subject device is also substantially equivalent to predicate device (K152558) regarding usage of X-ray accessories.