August 1, 2019

Elekta Instrument AB
Alf Laurell
Regulatory Affairs Engineer
Kungstensgatan 18
Stockholm, 10393 SE

Re: K190887
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: July 1, 2019
Received: July 3, 2019

Dear Alf Laurell:

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 Matthew Krueger
Assistant 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

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)*
K190887

Device Name
Leksell® Vantage™ Stereotactic System

Indications for Use *(Describe)*
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.

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

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: Mats Premfors, QA Manager

Date summary prepared: 2019-07-27

2. Trade Name

Leksell® Vantage™ Stereotactic System

3. Common Name

Stereotaxic instrument

4. Device Classification

Trade Name	Product Code	Class	Regulation Number
Leksell® Vantage™ Stereotactic System	HAW	II	21 CFR 882.4560

5. Classification Panel

Neurology

6. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell Stereotactic System	K080355
Leksell® Vantage™ Stereotactic System (Primary)	K171123

7. Other relevant submissions

N/A, no other relevant submissions

8. Device Description

The Leksell® Vantage™ Stereotactic System is a device used for minimally invasive neurosurgical procedures. It enables coordinate referencing and fixation of the patient's skull

and brain during image acquisition and treatment. The coordinate referencing enables target localization and accurate stereotactic treatment of brain targets; for example for aspirations and biopsies, electrode placements, injections of cells & drugs, heamatoma evacuations as well as lesioning using a number of methodologies.

The system consists of a head frame that is fixated to the patient skull by minimally invasive disposable fixation pins and a number of accessories for frame application and imaging as well as a stereotactic arc and operating room accessories for the sterile surgical procedure.

The system is based on the established Leksell center-of-arc principle, which allows guidance of compatible interventional instruments at any trajectory angle to the brain target. Compatible interventional instruments are based on the Leksell principle of an active working length of 190 mm (as the arc radius) and use the correct mechanical interfacing of the Arc instrument stop and guide holders. Various instruments, such as biopsy needles, cannulas, and electrodes can be used with the system to perform biopsies, hematoma evacuation and injections of radioactive nuclides and cytostatic agents, puncture of cysts, positioning electrodes for stimulation/ recording or lesioning and stereotactic endoscope guidance.

9. Summary of clinical testing

Clinical testing was deemed not required to demonstrate substantial equivalence with the predicate devices.

10. Summary of Non Clinical and Performance testing

The verification activities have covered requirements at system and subsystem level to show that the design output meet the design input.

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) was effective.

Results from verification and validation testing demonstrates that conformance to applicable technical requirement specifications and user needs have been met showing that the system is safe to use and is substantially equivalent to the predicate devices.

Testing is summarized in the table below.

Test	Test Method Summary	Results
Sterilization	Sterility validation (EtO) according to ISO 11135:2014 was performed to demonstrate that the device have a sterility assumed level (SAL) of 10-6. The tests were performed on the predicate device Leksell® Vantage™ Stereotactic System (K171123).	Results met pre-established acceptance criteria, demonstrating equivalence to the predicate device in terms of sterility.
MR testing	The device was subjected to compliance testing to applicable consensus safety standards, such as: ASTM F2052; ASTM F2119; ASTM F2182, ASTM F2213 and ASTM F2503, and FDA guidance regarding safety and compatibility in the MR environment.	The result demonstrates that the device is compliant to the FDA guidance and applicable consensus standards. This compliance demonstrates substantial equivalence.
Accuracy	Accuracy was tested on different levels of the subject device: - Total system accuracy from imaging to treatment. - Total mechanical accuracy of the system - Mechanical accuracy of each component - Handling accuracy of various steps like repeated mounting of parts to each other and scale setting accuracy. - Displacement from load of head when fixed in the frame.	All test cases were passed, demonstrating that the overall system accuracy of the Vantage system when used with the CT accessories is substantial equivalent to the predicate device.
Design and Usability validation	Design and usability validation of the system has been performed by trained competent and professionally qualified personnel to ensure that the product fulfils the intended use and user needs.	No unacceptable human factor risks were identified. Residual risks have been weighted against the benefit of the product and are deemed acceptable demonstrating that the Leksell® Vantage™ Stereotactic System used

		with the CT accessories is substantial equivalent to the predicate device.

11. 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.

12. Technological Characteristics

The CT accessories of Leksell® Vantage™ Stereotactic System has equivalent technological characteristics as its predicate device (K080355), for further details see the table below.

13. Substantial Equivalence

The intended use, the basic functionality and the fundamental technological characteristics of the device Leksell® Vantage™ Stereotactic System remain unchanged with the introduction of the CT accessories and the Leksell Vantage Head Frame Holder.

Leksell® Vantage™ Stereotactic as compared to the predicate devices has:

- Same mechanical accuracy
- Same coordinate system
- Same Center of Arc Principle
- Intended for localizing the same intracranial anatomical targets
- Used for the same clinical interventions and/or treatments
- Intended for use by the same health care professionals

In addition, the risk evaluation regarding endotoxin testing in routine production for product FirmFix™ 1 -5 has been updated.

The conclusion from verification and validation is that the Leksell® Vantage™ Stereotactic System is substantial equivalent to its predicate devices.

The table below shows a comparison between the Leksell® Vantage™ Stereotactic System and the predicate devices.

Issuer Alf Laurell	Ref nr/Dok nr/*Ref no/Doc no* --	*Edition* --
Regarding CT accessories for Leksell Vantage Stereotactic System		Directory --

	Subject Device	**Predicate Device** (K080355)	**Predicate Device** (K171123)
Device Name	Leksell® Vantage™ Stereotactic System	Leksell Stereotactic System® (K080355)	Leksell® Vantage™ Stereotactic System (K171123)
Regulation Number	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW	HAW	HAW
Product Class	II	II	II
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.
Technical Features	<u>Coordinate System:</u> Leksell Coordinate System using Cartesian coordinates <u>Fixation:</u> Head Frame applied to patient skull with four fixation pins. <u>Fixation Pins:</u> Single use Fixation Pins and Inserts that secures the Vantage head frame to the patient skull using Leksell Vantage Keys	<u>Coordinate System:</u> Leksell Coordinate System using Cartesian coordinates <u>Fixation:</u> Head Frame applied to patient skull with four fixation pins. <u>Fixation Pins:</u> Titanium Fixation Pins, Reusable Fixation Pins and Disposable Inserts that secures the Leksell Coordinate Frame G to the patient skull using Instrument Screw Drivers	<u>Coordinate System:</u> Leksell Coordinate System using Cartesian coordinates <u>Fixation:</u> Head Frame applied to patient skull with four fixation pins. <u>Fixation Pins:</u> Single use Fixation Pins and Inserts that secures the Vantage head frame to the patient skull using Leksell Vantage Keys
Imaging modality	CT and MR	CT and MR	MR
Technical characteristics	<u>CT accessories:</u> The Leksell Vantage CT Fiducial Box is used for referencing of the stereotactic coordinate system on the patient's anatomical CT images. <u>Leksell® Vantage™ Head Frame interface:</u>	<u>CT accessories:</u> The Open CT Indicator Box is used for referencing of the stereotactic coordinate system on the patient's anatomical CT images. <u>Leksell® Vantage™ Head Frame interface:</u>	<u>CT accessories:</u> N/A <u>Leksell® Vantage™ Head Frame interface:</u>

	Subject Device	**Predicate Device** (K080355)	**Predicate Device** (K171123)
	Leksell® Vantage™ Frame Holder is a modified OR adapter. In addition to holding the Leksell® Vantage™ Head Frame in the operating room, the Frame Holder is also interfacing the CT Fiducial box via one hole on each side.	N/A	Leksell® Vantage™ OR adapter
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;
Material	Invasive components: PEEK with Aluminum tip.	Invasive components: Aluminum or Titanium.	Invasive components: PEEK with Aluminum tip.
	Head Frame: Glass fiber reinforced Epoxy	Head Frame: Aluminum (with glued joints for insulation in MRI)	Head Frame: Glass fiber reinforced Epoxy

	Subject Device	**Predicate Device** (K080355)	**Predicate Device** (K171123)
	Arc: Aluminum	Arc: Aluminum	Arc: Aluminum
Accuracy	Mechanical accuracy 0,9 mm	Mechanical accuracy 0,9 mm	Mechanical accuracy 0,9 mm

Conclusion:

The conclusion is that the subject device is substantial equivalent to its predicate devices.