DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 15, 2017

Elekta Instrument AB
Matilda Forsberg
Regulatory Affairs Engineer
Kungstensgatan 18
Stockholm, 10393 SE

Re: K171123
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, 2017
Received: June 19, 2017

Dear Ms. Forsberg:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K171123

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 4- 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: 2017-09-14

2. Trade Name

Leksell® Vantage™ Stereotactic System

3. Common Name

Stereotaxic instrument

4. Device Classification

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

5. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell Stereotactic System	K080355

6. Other relevant submissions

Device	510(k) #
Leksell Stereotactic System, Injection/ Aspiration Needle Kit	K152558
Leksell Stereotactic System, Biopsy Needle Kit	K031980
Leksell Stereotactic System	K972324

7. 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.

8. Summary of clinical testing

Clinical testing was deemed not required to demonstrate substantial equivalence.

9. 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.

The table below summarize the performance testing performed, test method summary and result:

Test	Test Method Summary	Results
Biocompatibility	Biocompatibility testing were performed for those materials that come in contact with the patient. The tests were performed on the subject device according to ISO 10993-1, ISO 10993-5, ISO 10993-7 and ISO 10993-10.	All biocompatibility tests are reported to pass the respective biocompatibility requirements. Based on the results, knowledge of the material, exposure time and area and indication, the device is judged to be substantial equivalent to the predicate device from a biocompatibility perspective.
Sterilization – devices sold as sterile	Sterility validation (EtO) according to ISO 11135:2014 was performed to demonstrate that the devices have a sterility assurance level (SAL) of 10^{-6}. The tests were performed on the subject device.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility.
Sterilization – reusable parts	Reusable parts were validated for steam sterilization. The validation was performed with the intent to prove that the Leksell Vantage™ Arc System can obtain a sterility assurance level (SAL) of at least 10-6 when steam sterilized in 134°C-3 min or 132°C-4 min. The tests were performed on the subject device.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for reusable parts.
Cleaning – reusable parts	Reusable parts were validated for manual cleaning and cleaning with a washer-disinfector according to EN ISO 15883. The validation was performed with the intent to prove that the Leksell® Vantage™ System will be clean when using the methods described in the IFU. The tests were performed on the subject device by using artificial blood and detection of protein residues after cleaning.	All parts passed the final validation and met all pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of cleaning.

Shelf life and packaging/shipping testing	Shelf life and transport testing was performed on 3 years accelerated aged products according to ASTM F1980-07, ASTM F1886-09, ASTM F1929-15, ASTM F88-15, ISO 11607-1:2006/A1:2014, ASTM D4169-14, ISO 11737-2	All test were passed, demonstrating sterility after transport and shelf life of three years for the pre-sterilized parts, showing substantial equivalence to the predicate device.
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 standard. 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 is substantial equivalent to the predicate device.

Summary:
The components have been subjected to compliance testing to applicable consensus safety standards in order to support the MR conditional and MR safety claims. Testing has also been done to meet applicable biocompatibility and sterilization standards.

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 device.

10. 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.

11. Technological Characteristics

The Leksell® Vantage™ Stereotactic System has equivalent technological characteristics as its predicate device (K080355). It uses the same coordinate system and center-of-arc principle, which allows guidance of compatible interventional instruments at any trajectory angle to the brain target. Neurosurgical Instruments from Elekta (needles and cannulas) with a working length of 190 mm, previously cleared in the predicate devices K080355, K152558 and K031980, are also fully compatible with Leksell Vantage Stereotactic System.

12. Substantial Equivalence

The Leksell® Vantage™ Stereotactic System is built on the same technique as its predicate device Leksell Stereotactic System (K080355). It utilizes the same Center-of-Arc Principle with a 190 mm Arc radius for the introduction of neurosurgical instruments.

Leksell® Vantage™ Stereotactic System and the previously cleared Leksell Stereotactic System has/is:

- Same system 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 i.e.
- Intended for use by the same health care professionals

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

	Subject Device	Predicate Device
Device Name	Leksell® Vantage™ Stereotactic System	Leksell Stereotactic System® (K080355)
Regulation Number	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW	HAW
Product Class	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.
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
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;

	Subject Device	Predicate Device
Material	Invasive components: PEEK with Aluminum tip.	Invasive components: Aluminum or Titanium.
	Head Frame: Glass fiber reinforced Epoxy	Head Frame: Aluminum (with glued joints for insulation in MRI)
	Arc: Aluminum	Arc: Aluminum
Accuracy	Mechanical accuracy 0,9 mm	Mechanical accuracy 0,9 mm
Accessories	Neurosurgical Instruments with working length of 190 mm	Neurosurgical Instruments with working length of 190 mm

Conclusion:

The main differences to the predicate device is the frame material, made in a composite material, making it more suitable for MR imaging. Other improvements made are easier fixation and handling due to fewer components. The similarities are significant and the conclusion is that the device is substantial equivalent with the predicate device.