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

Elekta Instruments AB
% Ms. Matilda Forsberg
Regulatory Affairs Engineer
Kungstensgatan 18
Stockholm 10393
SWEDEN

August 4, 2015

Re: K151561
Trade/Device Name: Leksell Gamma Knife® Icon™
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: June 5, 2015
Received: June 10, 2015

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 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 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 yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151561

Device Name
Leksell Gamma Knife Icon

Indications for Use *(Describe)*

Leksell Gamma Knife® Icon™ 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, arteriovenous malformations, trigeminal neuralgia, medically refractory essential tremor, meningiomas, vestibular schwannomas, post-surgical pituitary adenomas and recurrent glioblastomas.

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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Section 4- 510(k) Summary

As Required by 21 CFR 807.92(c) 510 (k) Summary

1. Subscribers Name & Address

Elekta Instrument AB
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Official Correspondent: Ms Louise Wachtmeister

Date summary prepared: 2015-06-05

2. Trade Name

Leksell Gamma Knife® Icon™

3. Common Name

Medical charged-particle radiation therapy system

4. Device Classification

Trade Name	Product Code	Class	Regulation Number
Leksell Gamma Knife® Icon™	IWB	II	21 CFR 892.5750

5. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	Manufacturer	510(k) #
Leksell Gamma Knife® Perfexion™	Elekta Instrument AB	K133565
XVI R5.0	Elekta LTD.	K131965

6. Other relevant submissions

Devices	510(k) #
Leksell Stereotactic System	K080355
Leksell GammaPlan®	K103093
Nanor and Efficast/Nanor Hybrid Thermoplastic Materials	K131795

7. Device Description

Leksell Gamma Knife® Icon™ 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.

Based on preoperative radiological examinations, the Leksell Gamma Knife® Icon™ unit provides highly accurate external irradiation of intra-cranial structures using collimated beams of ionizing radiation.

Each unit contains 192 sealed sources of Cobalt 60.

The Leksell Gamma Knife Icon system consists of several parts, physically separated into a control room and a treatment room.

- The control room contains an operator console and an office cabinet. The treatment session is controlled and monitored by the operator from the control room. The control room also contains a Leksell GammaPlan computer.

- The treatment room contains the Leksell Gamma Knife unit. A Leksell Gamma Knife unit consists of the radiation unit, the patient positioning system, and a set of covers. A Leksell Gamma Knife Icon unit also includes a Cone Beam CT and an Intra Fraction Motion Management (IFMM) system. The treatment room also contains a camera, patient speakers, a microphone, a treatment room monitor, and a radiation warning lamp.

The system is electrically separated into an office side and a medical side.

- The office side consists of the equipment in the control room, as well as the following equipment in the treatment room: a camera, patient speakers, a microphone, a treatment room monitor and the radiation warning lamp. The office side is powered and controlled by the office cabinet in the control room.

- The medical side consists of the Leksell Gamma Knife unit in the treatment room, and is electrically isolated from the office side. The medical side is powered and controlled by a medical cabinet, placed inside the rear cover of the radiation unit.

8. Summary of Non Clinical and Performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against requirement specification. Regression and re-test of unchanged functionalities in the developed system was done to ensure that the new and updated functionalities did not introduce any undesirable effects.

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 new functionality was effective.

The system has been subjected to compliance testing to voluntary consensus safety standards, e.g. IEC 60601-1 Ed 3, IEC 60601-1-2 Ed 3, IEC 60601-1-3 Ed 2 and IEC 60601-2-11 Ed 3.

Results from verification and validation testing demonstrate that conformance to applicable technical requirement specification and user needs have been met and safety & effectiveness have been achieved.

9. Intended Use

Leksell Gamma Knife® Icon™ 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, arteriovenous malformations, trigeminal neuralgia, medically refractory essential tremor, meningiomas, vestibular schwannomas, post-surgical pituitary adenomas and recurrent glioblastomas.

10. Technological Characteristics

Leksell Gamma Knife Icon 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.

Compared to the previously cleared Leksell Gamma Knife Perfexion (K133565), the Leksell Gamma Knife Icon contains new fixation option of the patient with a mask, including a Cone Beam Computerized Tomography (CBCT) and an Intra Fraction Motion Management (IFMM) system**.** These additional features will give an option to patients to receive treatment without the need for the attachment of an invasive stereotactic frame.

The fundamental functionality and technical characteristics of the Gamma Knife unit have not changed and are substantially equivalent to the predicate device K133565.

11. Substantial Equivalence

Compared to the previously cleared Leksell Gamma Knife Perfexion (K133565), the Leksell Gamma Knife Icon contains new fixation option of the patient with a mask, including a Cone Beam Computerized Tomography (CBCT) and an Intra Fraction Motion Management (IFMM) system**.** The CBCT part is substantially equivalent to the predicate device XVI R5.O (K131965) and the fundamental functionality and technical characteristics of the Gamma Knife unit have not changed and is substantially equivalent to the previously cleared Leksell Gamma Knife Perfexion (K133565).

The conclusion is that the differences in technological characteristics between Leksell Gamma Knife Icon and the predicate devices do not raise questions of safety and effectiveness.