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

October 29, 2015

Elekta Instrument AB
% Ms. Matilda Forsberg
Regulatory Affairs Engineer
Kungstensgatan 18
SE-103 93 STOCKHOLM
SWEDEN

Re: K151159
Trade/Device Name: Leksell Gamma Knife Perfexion
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: September 25, 2015
Received: September 28, 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,

For

Robert Ochs, Ph.D.
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)*

Device Name
Leksell Gamma Knife Perfexion

Indications for Use *(Describe)*

Leksell Gamma Knife® Perfexion™ 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), and 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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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: Ms Louise Wachtmeister

Date summary prepared: 2015-04-22

2. Trade Name

Leksell Gamma Knife® Perfexion™

3. Device Classification

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

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
TrueBeam, TrueBeam STx, Edge	K140528
Leksell Gamma Knife® Perfexion™	K133565

5. Other relevant submissions

Devices	510(k) #
Leksell Steretocatic System	K080355
Leksell GammaPlan® PFX	K103093

6. Device Description

Leksell Gamma Knife Perfexion 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 Perfexion 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.

Leksell Gamma Knife Perfexion systems consists of several units, physically separated in an Office side in the control room and a Medical side in the treatment room.

- The medical side consists basically of the radiation unit with a patient positioning system. The system control and power units are placed inside the cover of the radiation unit.
- The office side consists of the operator console with control panel and office computer.

7. Summary of Clinical and Non Clinical testing

Clinical testing was not required to support substantial equivalence with the predicate devices. A risk analysis review was performed to investigate the impact from the new intended use. The conclusion was that the Leksell Gamma Knife® Perfexion is as safe and as effective as its predicate for the new indications.

8. Performance testing

The technical characteristics of the device has not changed compared to the previously cleared Leksell Gamma Knife® Perfexion K133565 and no new performance testing has been made.

9. Intended Use

Leksell Gamma Knife® Perfexion™ 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), and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors).

The intended patients are adults and children from the age of 2 years and up.

10. Technological Characteristics

This submission does not introduce any modifications to the device. The technical characteristics of the device are the same as the previously cleared Leksell Gamma Knife Perfexion K133565.

11. Substantial Equivalence

The intended use statement for the Leksell Gamma Knife Perfexion is similar to its predicate devices K140258 and K133565. The change to the intended use includes added indications typical to conditions in the head and the neck region that may be treated with stereotactic irradiation. The addition of these indications does not affect the safety and effectiveness of the device and fall within the previously cleared indications for use. The functionality and technical characteristics of the device have not changed from the previous submission and are substantially equivalent to the previously cleared device K133565.

The conclusion is that the Leksell Gamma Knife® Perfexion is as safe and as effective as its predicate for the new indications.