Elekta Instrument AB
% Mr. Alf Laurell
Regulatory Affairs Engineer
Kungstensgatan 18, P.O. Box 7593
SE 103 93 Stockholm
SWEDEN

March 30, 2018

Re: K173789
Trade/Device Name: Leksell Gamma Knife® Icon™
Leksell Gamma Knife® Perfexion™
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: February 22, 2018
Received: March 1, 2018

Dear Mr. 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173789

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**
- **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)**
- **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.

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."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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)*
K173789

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)
- 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.

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."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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: 2018-02-12

2. Trade Name

Leksell Gamma Knife® Icon™
Leksell Gamma Knife® Perfexion™

3. Device Classification

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

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	Manufacturer	510(k) #
Leksell Gamma Knife® Icon™	Elekta Instrument AB	K160440
Leksell Gamma Knife® Perfexion™	Elekta Instrument AB	K151159

5. Other relevant submissions

Devices	510(k) #
Leksell GammaPlan® v. 11.1	Pending 510(k)

6. Device Description

Leksell Gamma Knife® Icon™ and Leksell Gamma Knife® Perfexion™ are radiosurgery systems for use in the stereotactic irradiation of head 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 unit provides highly accurate external irradiation of intra-cranial structures using collimated beams of ionizing radiation.

7. Summary Clinical testing

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

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 control system against requirement specification.
Regression test of unchanged functionalities in the developed system was done to ensure that new and updated functionalities did not introduce any undesirable effects.

Design and usability validation of the system have 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 were effective.

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

Biocompatibility testing has been performed to ensure that all materials are biocompatible in relation to the use of the device.

9. Intended Use

Intended Use (Leksell Gamma Knife® Icon™):

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
- 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)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors).

Intended Use (Leksell Gamma Knife® Perfexion™):

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)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors).

10. Indications for use

Indications for use (Leksell Gamma Knife® Icon™):

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
- 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)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors).

Indications for use (Leksell Gamma Knife® Perfexion™):

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)
- Pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformations, cavernous malformations, skull base tumors).

11. Technological Characteristics

Leksell Gamma Knife® Icon™ and Leksell Gamma Knife® Perfexion™ are radiosurgery systems 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.

The fundamental technical characteristics of the Gamma Knife unit have not changed and are substantially equivalent to their predicate devices Leksell Gamma Knife® Icon™ (K160440) and Leksell Gamma Knife® Perfexion™ (K151159).

12. Substantial Equivalence

A new control system software version has been introduced to support Leksell Gamma Knife® Icon™ and Leksell Gamma Knife® Perfexion™.

The modified device Leksell Gamma Knife® Icon™ is claimed to be substantially equivalent to the predicate device Leksell Gamma Knife® Icon™ (K160440).
The modified device Leksell Gamma Knife® Perfexion™ is claimed to be substantially equivalent to the predicate device Leksell Gamma Knife® Perfexion™ (K151159).

The devices are substantially equivalent with regards to fundamental functionality, technical characteristics and Intended use.