November 22, 2019

Elekta Limited
% Ms. Irina Proutski
Senior Regulatory Affairs Consultant
Linac House, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

Re: K192242
Trade/Device Name: Precise Treatment System™, Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™ and Versa HD™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: August 6, 2019
Received: August 22, 2019

Dear Ms. Proutski:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K192242

Device Name
Precise Treatment System™, Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™ and Versa HD™

Indications for Use *(Describe)*

Entry-level EMLA (Synergy Platform/Synergy)
• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner.
• It is intended to assist a licenced medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard dose fractionation, hyperfractionation, and hypofractionation in all areas of the body where such treatment is indicated.
• The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body.

Mid-level EMLA (Infinity)
• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner.
• It is intended to assist a licenced medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard dose fractionation, hyperfractionation, hypofractionation and stereotactic delivery (stereotactic body radiation therapy – SBRT: stereotactic ablative radiotherapy – SABR) in all areas of the body where such treatment is indicated.
• The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body.

High-level EMLA (Versa HD)
• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner.
• It is intended to assist a licenced practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard fractionation, hyperfractionation, hypofractionation and stereotactic delivery (stereotactic body radiation therapy – SBRT: stereotactic ablative radiotherapy – SABR; stereotactic radio surgery - SRS) in all areas of the body where such treatment is indicated.
• The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body and for the treatment of functional disorders, such as trigeminal neuralgia.

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

K192242

The following information follows the format of 21 CFR 807.92

Date of preparation of summary: 25th October 2019

Submitted by:

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Contact name: Irina Proutski

Trade name: Precise Treatment System™, Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity ™ and Versa HD™

Common Name: Elekta Medical Linear Accelerator System

Classification Name: Medical Charged-Particle Radiation Therapy System
Accelerator, Linear, Medical, 21CFR 892.5050

Product Code: 90 IYE

Predicate Device: EMLA K182138

Product Description:

The Elekta Medical Linear Accelerator system is an image guided Radiation Therapy device to assist a licensed practitioner in the delivery of ionizing radiation to a defined target volume.

The system consists of components of the accelerator, such as, beam shaping, with imaging and accessories for patient positioning and set-up to deliver therapeutic treatments.

The Elekta Medical Linear Accelerator System is currently available in the following model variants – Precise Treatment System, Elekta Synergy Platform, Elekta Synergy, Elekta Infinity and Versa HD.

Intended Use / Indication For Use Statement:

Product	Proposed Indications for Use
Entry-level EMLA (Synergy[1]/Synergy Platform)	• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner. • It is intended to assist a licenced medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard dose fractionation, hyperfractionation, and hypofractionation in all areas of the body where such treatment is indicated. • The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body.
Mid-level EMLA (Infinity[2])	• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner.

[1] Synergy and Synergy Platform ads the Trade Names and are used with the Entry-level EMLA interchangeably

[2] Infinity is a Trade Name and used with Mid-level EMLA interchangeably

Addition of KV imaging (XVI)	• It is intended to assist a licenced medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard dose fractionation, hyperfractionation, hypofractionation and **stereotactic delivery (stereotactic body radiation therapy – SBRT: stereotactic ablative radiotherapy – SABR)** in all areas of the body where such treatment is indicated. • The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body.
High-level EMLA (Versa HD[3]) Addition of High Dose Rate Mode (HDRM)	• The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licenced medical practitioner. • It is intended to assist a licenced practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions using standard fractionation, hyperfractionation, hypofractionation and **stereotactic delivery (stereotactic body radiation therapy – SBRT: stereotactic ablative radiotherapy – SABR; stereotactic radio surgery - SRS)** in all areas of the body where such treatment is indicated. • The EMLA is indicated for the delivery of curative and palliative intent EBRT to Adult and Pediatric patients with primary benign and malignant tumor and metastasis (or secondaries) anywhere in the body and **for the treatment of functional disorders, such as trigeminal neuralgia.**

Whilst the Indications for Use statement is restructured into three statements, these updates do not represent significant changes and serve primarily to improve clarity on capabilities of each configuration.

Summary of Technological Characteristics:

This premarket notification is not related to any change in the technological characteristics of the medical linear accelerator system and these are unchanged from those of the previously cleared medical device (EMLA, K182138) or the software used in the device. There are no novel forms of technology introduced in this premarket notification.

Substantial Equivalence

The functionality of the Elekta Medical Linear Accelerator system is substantially equivalent to that of its predicate device EMLA K182138 in safety and effectiveness. The principles of operation and technological characteristics are substantially equivalent.

Summary of performance testing (non-clinical)

Testing in the form of module, integration and system level verification was included in the previous submission K182138. Since no changes to the hardware or software was made in this submission, no additional non-clinical testing has been conducted. The bench testing provided in the previous submission still applies.

Summary of performance testing (clinical)

[3] Versa HD is a Trade Name and used with High-level EMLA interchangeably

The only change in this submission concern Indications for Use. An extensive literature search was conducted to collect and analyze available clinical evidence in order to support new Indications for Use.

Conclusion:

An analysis of scientific literature demonstrated that the proposed Indications for Use are supported by existing clinical evidence. The Elekta Medical Linear Accelerator system continues to be safe and effective and it is substantially equivalent to the predicate device.