Elekta Limited
℅ Mr. Lorenzo Muratori
Regulatory Affairs and Compliance Engineer
Linac House, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

June 11, 2021

Re: K210500
Trade/Device Name: Elekta Synergy, Elekta Harmony, Elekta Infinity, Versa HD
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE,
Dated: February 18, 2021
Received: February 22, 2021

Dear Mr. Muratori:

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,

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210500

Device Name
Elekta Medical Linear Accelerator

Indications for Use *(Describe)*
The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licensed medical practitioner.

It is intended to assist a licensed medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation.

−Elekta Synergy and Elekta Harmony are the default entry-level configurations. They are 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.

−Elekta Infinity is the default mid-level configuration. 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.

−Versa HD is the default high-level configuration. 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 and for the treatment of functional disorders, such as trigeminal neuralgia.

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.

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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TRADITIONAL 510(k) SUMMARY K210500

The following information follows the format of 21 CFR 807.92

I. SUBMITTER

Date of preparation: 18 February 2021

Submitted by: Elekta Limited
Linac House, Fleming Way, Crawley, West Sussex
RH10 9RR, United Kingdom
Telephone: +44 (0)1293 654836

Contact name: Lorenzo Muratori

II. DEVICE

Trade Name: Elekta Synergy®, Elekta Harmony™, Elekta Infinity ™, Versa HD™

Common Name: Elekta Medical Linear Accelerator (ELMA)

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

Product Code: IYE

III. PREDICATE DEVICE K192242

IV. DEVICE DESCRIPTION

The Elekta Medical Linear Accelerator (EMLA) 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 Harmony being introduced with this pre-market notification submission.

The EMLA offers multiple treatment modalities including photon energies in the range of 4 – 25 MV and electron energies in the range of 4 – 22 MeV. Un-flattened and flattened photon energies are available. A treatment table, located in the treatment room, allows the patient to be accurately positioned to receive the prescribed radiotherapy and supports the patient during treatment. The table is capable of linear and rotational movements. The EMLA is equipped with a MV portal imaging sub-system, i.e. iViewGT, and an optional kV imaging sub-system, i.e. XVI. The user interface controlling devices are located partly in the treatment room and partly in the control room.

V. INTENDED USE / INDICATION FOR USE STATEMENT

The Elekta Medical Linear Accelerator (EMLA) is intended to be used for external beam radiation therapy (EBRT) treatments as determined by a licensed medical practitioner.

It is intended to assist a licensed medical practitioner in the delivery of EBRT to defined target volumes, while sparing surrounding normal tissue and critical organs from excess radiation.

- Elekta Synergy and Elekta Harmony are the default entry-level configurations. 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.
- Elekta Infinity is the default mid-level configurations. 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.
- Versa HD is the default high-level configuration. 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 and for the treatment of functional disorders, such as trigeminal neuralgia.

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.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The vast majority of technological characteristics are the same, however, there are some changes. All the changes are to be considered minor in respect of the complexity of technology employed in the EMLA.

The Elekta Harmony variant features improved user interface controls in the treatment room, a patient support system capable of motorized linear movement along the longitudinal, lateral and vertical directions and manual movement around the column axis, but it does not support the motorized rotational movement around the isocentre axis as the predicate device does. The Elekta Harmony model can be installed in a bunker up to 500cm smaller than the other models of the EMLA family. The Elekta Harmony imaging device panels are permanently deployed, while those of the predicate device are foldable.

There are no novel forms of technology introduced in this premarket notification.

VII. SUMMARY OF PERFORMANCE TESTING (NON-CLINICAL)

Development, verification and validation activities for the modified system were carried out in accordance with design controls as required by FDA's Quality System Regulation (21 CFR §820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 Risk Management requirements, and IEC 62304 requirements for software life-cycle processes. Non-clinical testing was performed to

evaluate device performance and functionality in accordance with design and risk management requirements at subsystem, integration and system levels including interoperability. This includes the essential performance defined by Elekta. Basic safety and essential performance of the individual subsystems and the integrated EMLA system have been satisfied through conformance with the applicable general, particular and collateral safety and essential performance standards for medical devices.

Documentation of software development and verification testing activities for each subsystem of the EMLA system is maintained in accordance with FDA's "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,*" May 2005, for devices that pose a major level of concern (Class C per IEC 62304).

Formal validation of the clinical workflows has been performed on a clinically representative production equivalent system by competent and professionally qualified personnel.

VIII. CONCLUSION DRAWN FROM TESTS

The verification and validation non-clinical test results demonstrate compliance with the applicable consensus standards and that the functional and performance requirements defined by Elekta are met. We therefore conclude that the device is as safe, as effective, and performs as well as or better than the legally marketed device.

IX. SUBSTANTIAL EQUIVALENCE

Elekta Harmony is substantially equivalent to the predicate devices cleared under K192242 in intended use and indications for use, principles of operation, technological characteristics, performance, and labelling.