ELEKTA LIMITED
% Mr. Andrew Hedges
Principal Engineer - RA and Compliance
Linac House, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

September 5, 2018

Re: K182138
Trade/Device Name: Precise Treatment System™; Synergy® platform; Synergy®; Infinity ™; VersaHD ™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: July 31, 2018
Received: August 7, 2018

Dear Mr. Hedges:

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.

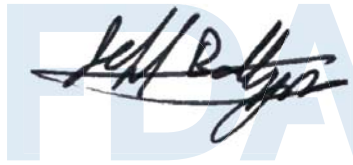
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*

K182138

Device Name

Precise Treatment System, Synergy Platform, Synergy, Infinity and Versa HD

Indications for Use *(Describe)*

The Elekta Medical Linear Accelerator is indicated to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation for treatment that includes but is not limited to, malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

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

The following information follows the format of 21 CFR 807.92

Date of preparation of summary: 31th July 2018

Submitted by:

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Contact name: Andrew Hedges

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

Common Name: Medical Linear Accelerator System

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

Product Code: 90 IYE

Predicate Device: Elekta Limited, K123808 Agility, K051932 Elekta Synergy

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:

The Elekta Medical Linear Accelerator is indicated to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation for treatment that includes but is not limited to, malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

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. Elekta has introduced changes to the control software, Integrity™, primarily to provide tighter error detection and to merge the codebase to provide a single release that supports the current hardware platform. 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 Agility K123808 and its associated linear accelerator, devices in safety and effectiveness. The intended use of the system, principles of operation, technological characteristics are substantially equivalent.

Summary of performance testing (non clinical)

Testing in the form of module, integration and system level verification was conducted in accordance with FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard, IEC 62304 Software life-cycle processes, and the other FDA recognised consensus standards which includes but is not limited to IEC 60601-1, IEC 60601-2-1, IEC 60601-1-6, IEC 62366-1. Software verification testing was conducted and documented in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for devices that pose a major level of concern (Class C per IEC 62304). Basic safety and essential performance have been satisfied through conformance with device-specific recognised consensus standards, as well as applicable general and collateral safety and essential performance standards for medical devices.

Validation of the integrated system under clinically representative conditions has been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specifications have been met and safety & effectiveness has been achieved.

Conclusion:

The results of verification, validation and safety standard testing demonstrate that the Elekta Medical Linear Accelerator system is substantially equivalent to their predicate device.