January 15, 2026

Elekta Solutions AB
Lorenzo Muratori
Senior Regulatory Affairs Engineer
Hagaplan 4
Stockholm, 11368
Sweden

Re: K252188
Trade/Device Name: EMLA (Elekta Evo); EMLA (VersaHD); EMLA (Elekta Harmony Pro); EMLA (Elekta Infintiy); EMLA (Elekta Harmony); EMLA (Elekta Synergy)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 18, 2025
Received: December 18, 2025

Dear Lorenzo 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252188

Please provide the device trade name(s).

EMLA (Elekta Evo);
EMLA (VersaHD);
EMLA (Elekta Harmony Pro);
EMLA (Elekta Infintiy);
EMLA (Elekta Harmony);
EMLA (Elekta Synergy)

Please provide your Indications for Use below.

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 and Elekta Harmony Pro are 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 and Elekta Evo are 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

	Elekta Solutions AB Hagaplan 4 Box 7593 Stockholm, ZIP 113 68 Sweden
Contact:	Lorenzo Muratori Lorenzo.Muratori@elekta.com
Establishment Registration #:	3015232217
510(k) Number:	K252188
Date Prepared:	11 July 2025

II. DEVICE

Trade Name:	EMLA (Elekta Evo); EMLA (VersaHD); EMLA (Elekta Harmony Pro); EMLA (Elekta Infintiy); EMLA (Elekta Harmony); EMLA (Elekta Synergy)
Product Classification:	Class II
Common Name:	Medical charged-particle radiation therapy system
Regulation Number:	21 CFR § 892.5050
Classification name:	Accelerator, Linear, Medical
Product Code:	IYE

III. PREDICATE DEVICE

Predicate Device #:	K210500
Predicate Trade Name:	Elekta Synergy, Elekta Harmony, Elekta Infinity, Versa HD

IV. DEVICE DESCRIPTION

The Elekta Medical Linear Accelerator (EMLA) is an external beam, image guided Radiation Therapy device to assist a licensed practitioner in the delivery of ionizing radiation to a defined target volume. The system is located in a radiation-shielded treatment room and consists of several sub-systems, such as, the electron accelerator, beam shaping, imaging, computerized control systems and a treatment table to support the patient with accessories for patient positioning and set-up to deliver therapeutic treatments.

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 table is capable of linear and rotational movements. The user interface controlling devices are located partly in the treatment room and partly in the control room.

The EMLA is made available in the following models: Elekta Synergy, Elekta Harmony, Elekta Infinity, Elekta Harmony Pro, Versa HD, Elekta Evo. The major differences are described in section VII.

V. INTENDED USE / INDICATION for USE

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 and Elekta Harmony Pro are 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 and Elekta Evo are 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. INDICATIONS FOR USE COMPARISON

The Indications for Use of the subject device are the same as the predicate device.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The majority of technological characteristics are the same, however, there are some differences.

The feature comparison chart below shows the difference between the predicate and the subject device.

Technological characteristic	Predicate Device (K210500)				Subject Device						Same/Different	Summary of technological characteristic/ Summary of comparison
	Elekta Synergy	Elekta Harmony	Elekta Infinity	Versa HD	Elekta Synergy	Elekta Harmony	Elekta Infinity	Elekta Harmony Pro	Versa HD	Elekta Evo		
Size of the treatment room	EMLA regular size	Up to 500 cm smaller than EMLA regular size	EMLA regular size	EMLA regular size	EMLA regular size	Up to 500 cm smaller than EMLA regular size	EMLA regular size	EMLA regular size	EMLA regular size	EMLA regular size	Similarity	Harmony Pro is made available for installation in an EMLA regular size bunker
User interface controls	Synergy HHC and UIM	Harmony HHC and UIM	Infinity HHC and UIM	Versa HD HHC and UIM	Synergy HHC and UIM	Harmony HHC and UIM	Infinity HHC and UIM	Harmony HHC and UIM	Versa HD HHC and UIM	Versa HD HHC and UIM	Same	The Hand Held Controller (HHC) and the User Interface Module (UIM) have some variations between different EMLA models. The subject devices have the same HHC and UIM of the predicate devices.
Linear accelerator (Linac)	The Linac encompasses the sub-system that generates the treatment MV radiation. (Common to all models)				The Linac encompasses the sub-system that generates the treatment MV radiation. (Common to all models)						Same	The basic mechanical structure is based on a 360° rotating gantry and a 360° rotating collimator that mounts the Beam Limiting Device. The construction allows the treatment beam to be delivered from any angle around the patient, who is typically positioned on the Patient Support System
Linac treatment control system	The component that controls the function of the linac. It is constituted by two major components: a real-time and a non-real time. (Common to all models)				The component that controls the function of the linac. It is constituted by two major components: a real-time and a non-real time. (Common to all models)						Different	The control system of the subject device has improvements to cybersecurity. It enables compliance with the IEC 60601-2-1 Ed. 4. It supports an integrated beam gating interface in compliance with the IEC 60601-2-1 Ed. 4.
Photon Energy	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6,	Flat Beam: 6MV only FFF Beam: 6MV only	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6,	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6,	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam:	Flat Beam: 6MV only FFF Beam: 6MV only	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6, 10MV	Flat Beam: 6, 10, 15MV FFF Beam: 6, 10MV	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6, 10MV	Flat Beam: 4, 6, 8, 10, 15, 18, 25 MV FFF Beam: 6, 10MV	Difference	Elekta Harmony Pro supports more energies than the predicate Elekta Harmony. Elekta Evo supports the same energies as the predicate Versa HD. The other models: the subject devices have the same characteristics as the predicate

Technological characteristic	Predicate Device (K210500)				Subject Device						Same/Different	Summary of technological characteristic/ Summary of comparison
	Elekta Synergy	Elekta Harmony	Elekta Infinity	Versa HD	Elekta Synergy	Elekta Harmony	Elekta Infinity	Elekta Harmony Pro	Versa HD	Elekta Evo		
	10MV		10MV	10MV	6, 10MV							
Photon Dose Rate	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	6MV: 500 MU/min 6MV FFF: 1400 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	6MV: 500 MU/min 6MV FFF: 1400 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	6, 10 MV: 500 MU/min 15 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	4 MV - 230 MU/min 6, 8, 10, 25 MV: 500 MU/min 15, 18 MV: 600 MU/min 6MV FFF: 1400 MU/min 10MV FFF: 2200 MU/min	Same	Each energy is delivered with the same dose rate in every model of the predicate and the subject device
Electron Energy and dose rate	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV (22 MeV with MLCi2, not Agility) 600 Mu/min	NA	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV 600 Mu/min	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV 600 Mu/min	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV (22 MeV with MLCi2[1], not Agility) 600 Mu/min	NA	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV 600 Mu/min	6, 8, 9 or 10, 12, 15 MeV 600 Mu/min	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV 600 Mu/min	4, 6, 8, 9 or 10, 12, 15, 18, 20 MeV 600 Mu/min	Difference	Elekta Harmony Pro supports electron energies, while the predicate Elekta Harmony does not. Elekta Evo supports the same energies as the predicate Versa HD. The other models: the subject devices have the same characteristics as the predicate
Electron High Dose Rate (Total Skin Mode)	4 to 10 MeV: 3000 MU/min	NA	4 to 10 MeV: 3000 MU/min	4 to 10 MeV: 3000 MU/min	4 to 10 MeV: 3000 MU/min	NA	4 to 10 MeV: 3000 MU/min	NA	4 to 10 MeV: 3000 MU/min	4 to 10 MeV: 3000 MU/min	Identical	Elekta Harmony Pro does not support the Electron High Dose Rate (Total Skin Mode), same as its predicate Harmony. Elekta Evo supports the Electron High Dose Rate (Total Skin Mode), same as its predicate Versa HD.

Technological characteristic	Predicate Device (K210500)				Subject Device						Same/Different	Summary of technological characteristic/ Summary of comparison
	Elekta Synergy	Elekta Harmony	Elekta Infinity	Versa HD	Elekta Synergy	Elekta Harmony	Elekta Infinity	Elekta Harmony Pro	Versa HD	Elekta Evo		
												The other models: the subject devices have the same characteristics as the predicate
Beam shaping (MLC – Multi Leaves Collimator)	Agility BLD or MLCi2 BLD	Agility BLD			Agility BLD						Same	The MLC forms the end of the gantry arm that rotates around the treatment area of the patient and modifies the beam shape in accordance with the predefined treatment plan to accurately match the target volume. The predicate device Synergy supports both the Agility BLD and MLCi2 BLD, while the subject device Synergy supports the Agility BLD. The performance of Agility covers the performance of MLCi2. The other models: the subject devices have the same characteristics as the predicate
Delivery technique	Conformal Radiation Therapy (CRT) without Image Guided adiation Therapy (IGRT), Intensity-Modulated Radiation Therapy (IMRT) or Volumetric Modulated Arc Therapy (VMAT) delivered using IGRT (Common to all models)				Conformal Radiation Therapy (CRT) without Image Guided adiation Therapy (IGRT), Intensity-Modulated Radiation Therapy (IMRT) or Volumetric Modulated Arc Therapy (VMAT) delivered using IGRT (Common to all models)						Same	The subject devices have the same characteristics as the predicate
Patient Support System with a couch top	Precise Treatment Table (with iBEAM® evo Couchtop EP)	4-axis Table (with iBEAM® evo Couchtop EH)	Precise Treatment Table (with iBEAM® evo Couchtop EP)	Precise Treatment Table (with iBEAM® evo Couchtop EP) **or** Precise Treatment Table (with HexaPOD evo RT System)	Precise Treatment Table (with iBEAM® evo Couchtop EP)	4-axis Table (with iBEAM® evo Couchtop EH)	Precise Treatment Table (with iBEAM® evo Couchtop EP)	4-axis Table (with iBEAM® evo Couchtop EH)	Precise Treatment Table (with iBEAM® evo Couchtop EP) **or** Precise Treatment Table (with HexaPOD evo RT System)	Precise Treatment Table (with iBEAM® evo Couchtop EP) **or** Precise Treatment Table (with HexaPOD evo RT System)	Same	Harmony Pro has the same Patient Support System with couch top as Harmony. Elekta Evo has one of the two Patient Support System with couch top of Versa HD, i.e. HexaPOD evo RT System, which has the highest performance. The other models: the subject devices have the same characteristics as the predicate
MV Imaging	The iViewGT™ imaging system is an				The iViewGT™ imaging system is an Electronic Portal Imaging Device (EPID).						Same	It provides the MV IGRT solution that uses the

510(K) SUMMARY

Technological characteristic	Predicate Device (K210500)				Subject Device						Same/Different	Summary of technological characteristic/ Summary of comparison
	Elekta Synergy	Elekta Harmony	Elekta Infinity	Versa HD	Elekta Synergy	Elekta Harmony	Elekta Infinity	Elekta Harmony Pro	Versa HD	Elekta Evo		
device control system and imaging function	Electronic Portal Imaging Device (EPID). (Common to all models)				(Common to all models)							X-ray radiation of the digital accelerator and an MV detector panel to capture an image of the patient. The image shows the position of the patient in relation to the radiation beam. The imaging function is the same. However, the control system of the subject device has improvements to cybersecurity.
MV Imaging panel deployment	Retractable and foldable	Retractable	Retractable and foldable	Retractable and foldable	Retractable and foldable	Retractable	Retractable and foldable	Retractable	Retractable and foldable	Retractable and foldable	Identical	Harmony and Harmony Pro imaging panels can not be folded, while maintaining the retractable functionality.
KV Imaging device control system and imaging functions	The XVI imaging system is an electronic imaging device for kV image acquisition. (Common to all models)				The XVI imaging system is an electronic imaging device for kV image acquisition. (Common to all models. Image quality improved)			The XVI imaging system is an electronic imaging device for kV image acquisition. (Common to all models. Image quality improved. A CBCT High Definition (HD) reconstruction solution with further improved CBCT image quality is available in the pelvic anatomies, commercially referenced as Iris)			Difference	The control system of the subject devices has improvements to cybersecurity. The volume reconstruction function of all the subject devices has been improved. The volume reconstruction method used in the predicate devices (based on the reconstruction algorithm Feldkamp-Davis-Kress (FDK)) has been improved and adopted by all the subject devices. This results in improved image quality. The subject devices Versa HD, Elekta Harmony Pro and Elekta Evo also support a new CBCT reconstruction method with further improved image quality in the pelvic anatomies. It includes an AI-ML based component to estimate the scatter to enable its automatic removal from the projection images acquired by the imager ahead of the volume reconstruction.
KV Imaging panel deployment	Retractable and foldable	Retractable	Retractable and foldable	Retractable and foldable	Retractable and foldable	Retractable	Retractable and foldable	Retractable	Retractable and foldable	Retractable and foldable	Identical	Harmony and Harmony Pro imaging panels can not be folded, while maintaining the retractable functionality.
Beam Gating interface to external Patient Positioning Monitoring Systems	Elekta Response				Elekta Integrated Beam Gating interface						Difference	The predicate devices use the Elekta Response, which is a proprietary interface. The subject devices use the Integrated gating interface, which has been designed to comply with the IEC60601-2-1:2020 standard and is based on the NEMA RT 1-2014 standard.

Technological characteristic	Predicate Device (K210500)				Subject Device						Same/Different	Summary of technological characteristic/ Summary of comparison
	Elekta Synergy	Elekta Harmony	Elekta Infinity	Versa HD	Elekta Synergy	Elekta Harmony	Elekta Infinity	Elekta Harmony Pro	Versa HD	Elekta Evo		
												However, there are a few discrepancies between the two standards and in such cases the requirements of the IEC60601-2-1 standard take precedence.

A 3D CBCT reconstruction pipeline is a set of chained software filters that pre-process 2D projection images and create a 3D volume image from the 2D projections. The 3D CBCT image reconstruction pipeline supported by the legally marketed EMLA implements a reconstruction pipeline based on the reconstruction algorithm Feldkamp-Davis-Kress (FDK). The defining characteristic of the Elekta Harmony Pro, VersaHD and Elekta Evo is the introduction of an additional reconstruction pipeline, called High Definition Reconstruction which implements an iterative reconstruction method (Polyquant) which uses ordered subset and steepest descent with total variation regularization to reconstruct the 3D image and takes the spectral properties of the x-ray beam into account. The High Definition Reconstruction implements a scatter correction method using a machine learning method where a neural network is trained to estimate scatter in the projection domain. Simulated Monte Carlo data is used to train the network.

With this change, both reconstruction pipelines are supported by the Elekta Harmony Pro, VersaHD and Elekta Evo.

The High Definition Reconstruction pipeline will be supported for pre-selected anatomies only (currently the pelvic anatomies). The user will have the opportunity to choose which method they want to use, and the system will launch the appropriate reconstruction function.

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

VIII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Development, verification and validation activities have been 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, IEC 62304 requirements for software life-cycle processes and other FDA recognized consensus standards. Basic safety and essential performance of the EMLA have been satisfied through conformance with the applicable general, particular and collateral safety and essential performance standards for medical devices listed below and by establishing additional risk control measures.

Standards	
Standard No.	**Standard Title**
ANSI AMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-1 Edition 4.0 2020-10	Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
IEC 60601-2-68 Edition 1.0 2014-09	Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
IEC 60601-1-3 (to the extent required normatively by the IEC 60601-2-68)	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 61217:2011-12 Edition 2.0	Radiotherapy equipment - Coordinates, movements and scales
IEC 60976:2007-10 Edition 2.0	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 60601-1-2:2014 including AM1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic
ISO 14971:2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Application of usability engineering to medical devices
IEC 62304:2006 / A1:2016	Medical device software - Software life-cycle processes
ISO 20417:2021-04 1.0 Edition	Medical devices - Information to be supplied by the manufacturer
ISO 15223-1:2021-07 4.0 Edition	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
CR 34971:2022	Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning
ISO 10993-1:2018-08 5th Edition	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Documentation of software development and verification testing activities is maintained in accordance with FDA's "*Guidance Content of Premarket Submissions for Device Software Functions,*" June 2023.

The software for this device was considered as "enhanced documentation" level since a failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

All the subject devices: they feature the same patient-contact materials of the predicate devices. Therefore, test data acquired on the predicate devices support conformance to ANSI/AAMI/ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1".

All the subject devices: test data acquired on the predicate devices have been used to demonstrate substantial equivalence of the subject device, where performance depends only on technological characteristics which are the same on both devices.

Elekta Harmony Pro and the Elekta Evo: beam uniformity is supported by test data acquired on the predicate devices on the basis that the beam generation and shaping sub-systems are the same for each energy.

All the subject devices: verification of performance of the FDK based reconstruction function to generate CBCT images suitable for IGRT with improved imaged quality compared to the predicate device was completed and summarized:

- Image quality evaluation was performed for the FDK based reconstruction function, using acquired image quality phantom data, to evaluate uniformity, spatial resolution, low contrast visibility, and geometric accuracy in accordance with IEC 60601-2-68;
- Image registration accuracy evaluation was performed for FDK based reconstruction function, using phantom data and CT reference data;

Elekta Harmony Pro, Versa HD and the Elekta Evo: verification of performance of the HD Reconstruction function to generate CBCT images suitable for IGRT with improved imaged quality in the pelvic anatomies compared to the FDK based reconstruction function was completed and summarized below:

- Image quality comparison was performed between HD Reconstruction function and FDK based reconstruction function, using data acquired on phantom data, to evaluate uniformity, spatial resolution, low contrast visibility, and geometric accuracy in accordance with IEC 60601-2-68.
- Image quality comparison was performed between HD Reconstruction function and FDK based reconstruction function, using a total of 124 different clinical data sets, to evaluate uniformity, Hounsfield Unit consistency, signal-to-noise ratio, contrast-to-noise ratio, and contrast consistency.
- Image registration accuracy comparison was performed between HD Reconstruction function and FDK based reconstruction function, using phantom data and CT reference data.
- Image registration accuracy comparison was performed between HD Reconstruction function and FDK based reconstruction function, using a total of 13 different clinical patient CBCT projection data sets and CT reference data.
- A clinical image quality evaluation was performed between HD Reconstruction function and FDK based reconstruction function, using clinical patient data,

where user qualitatively compared image quality between the predicate device and the subject device and reported improved image quality.

Conclusion from the tests

Test results showed conformance of the subject devices to the applicable consensus standards, Elekta defined performance specifications and associated risk management requirements.

The conclusion from performance tests carried out to demonstrate the ability of the improved FDK based reconstruction function to reconstruct a CBCT volume image which is suitable for visualizing anatomies to enable certain clinical judgment, and which is suitable for automatic registration with a specified precision is that the subject device has improved image quality in uniformity, volume outline and spatial resolution, with no adverse impact to the accuracy of registration.

Elekta Harmony Pro, Versa HD and the Elekta Evo:
the conclusion from performance tests carried out to demonstrate the ability of the HD reconstruction function to reconstruct a CBCT volume image which is suitable for visualizing the pelvic anatomies to enable certain clinical judgment, and which is suitable for automatic registration with a specified precision is that image quality has improved in terms of a better uniformity and HU accuracy. In several cases, improved image quality results in better performance of the automatic registration function, not requiring any manual adjustment post registration. A clinical survey shows a preference towards the HD Reconstruction of the subject device over the predicate.

Formal validation of the clinical workflows has been performed by competent and professionally qualified personnel.

IX. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with thepredicate device.

X. SUBSTANTIAL EQUIVALENCE CONCLUSION

The subject devices have the same intended use as the predicate devices. The changes in the technological characteristics do not raise different questions of safety and effectiveness.

Non-clinical testing only was used to evaluate the performance, safety and effectiveness of the subject device. The methods are scientifically acceptable and based on FDA guidance and recognized consensus standards. The test results demonstrate that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the new and modified EMLA models are substantially equivalent to the EMLA models cleared under K210500 (predicate devices).