Elekta Solutions AB
% Ms. Melinda Smith
Director, Regulatory Affairs & Quality - Americas
Elekta, Inc.
400 Perimeter Center Ter, NE Suite 50
ATLANTA GA 30346

October 1, 2021

Re: K212114
Trade/Device Name: Elekta Unity
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: June 30, 2021
Received: July 7, 2021

Dear Ms. Melinda Smith:

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)*

K212114

Device Name

Elekta Unity

Indications for Use *(Describe)*

Elekta Unity using Magnetic Resonance Imaging is indicated for radiation therapy treatments and stereotactic radiation treatments of malignant and benign diseases anywhere in the body as determined by a licensed medical practitioner in accordance with a defined treatment plan.

Elekta Unity is intended for use with compatible Treatment Planning and Oncology Information Systems. The Elekta Unity 1.5T MR scanner is a magnetic resonance imaging system that produces cross-sectional images in any orientation of the internal structure of the whole body before, during, and after the radiotherapy treatment.

When interpreted by a trained physician magnetic resonance images acquired before, during, and after the radiotherapy treatment yield information that can be useful in diagnosis and may assist therapy planning, patient positioning and treatment delivery related to radiation oncology.

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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FORM FDA 3881 (6/20) **Page 1 of 1** PSC Publishing Services (301) 443-67

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

I. SUBMITTER

	Elekta Solutions AB Kungstensgatan 18 Box 7593 Stockholm, SE SE10393
Contact:	Melinda Smith, MS, RAC, CBA Melinda.Smith@elekta.com
Establishment Registration #:	3015232217
510(k) Number:	K212114
Date Prepared:	30 June 2021

II. DEVICE

Trade Name:	Elekta Unity
Product Classification:	Class II
Common Name:	Radiation charged-particle radiation system
Regulation Number:	21 CFR § 892.5050
Regulation Description:	Medical charged-particle radiation therapy system
Product Code:	IYE, LNH

III. PREDICATE DEVICE

Predicate Device: Elekta Unity (K192482)
Reference Devices: Philips Ingenia (K193215) and Elekta EMLA (K192242)

IV. DEVICE DESCRIPTION

Elekta Unity is a multifunctional digital linear accelerator designed to assist licensed medical practitioners in the delivery of ionizing radiation to defined volumes (e.g. malignant and benign tumors). Elekta Unity is capable of both intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT).

The Elekta Unity 1.5T MRI scanner is a magnetic resonance imaging sub-system that produces cross-sectional images in any orientation of the internal structure of the whole body before, during, and after the radiotherapy treatment.

When interpreted by a trained physician the images acquired before, during, and after the radiotherapy treatment yield information that can be useful in diagnosis and may assist therapy planning, patient positioning and treatment delivery related to radiation oncology.

In addition to the MRI sequences cleared with the predicate device, the subject device Elekta Unity configuration has the ability to generate images using following techniques, before, during or after treatment:

- **Introduce 3D Vane**
  3D Vane XD is a free breathing acquisition method that can be used to compensate for respiratory motion and peristalsis in 3D/FFE and 3D/TFE body imaging.
- **Introduce CS-Sense – compressed images**
  Compressed SENSE is an acceleration technique that is less sensitive to noise allowing increased resolution and/or coverage without a scan time penalty.
- **Introduce Breath Hold (BH)**
  Breath-hold is a technique where an image is acquired when a patient holds their breath in a defined phase of the breathing cycle.

V. INTENDED USE

Elekta Unity is intended for radiation therapy treatments and stereotactic radiation treatments of malignant and benign diseases anywhere in the body under MRI guidance as determined by a licensed medical practitioner in accordance with a defined treatment plan. The Indications for Use statement defines the disease or condition to be treated (or diagnosed for MR functions).

VI. INDICATIONS FOR USE

Elekta Unity using Magnetic Resonance Imaging is indicated for radiation therapy treatments and stereotactic radiation treatments of malignant and benign diseases anywhere in the body as determined by a licensed medical practitioner in accordance with a defined treatment plan.

Elekta Unity is intended for use with compatible Treatment Planning and Oncology Information Systems. The Elekta Unity 1.5T MR scanner is a magnetic resonance imaging system that produces cross-sectional images in any orientation of the internal structure of the whole body before, during, and after the radiotherapy treatment.

When interpreted by a trained physician magnetic resonance images acquired before, during, and after the radiotherapy treatment yield information that can be useful in diagnosis and may assist therapy planning, patient positioning and treatment delivery related to radiation oncology.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Elekta Unity is designed specifically to facilitate IGRT. Both, current and predicate device configurations use the same medical linear accelerator (linac) to deliver photon energies and dose rates for targeted external beam radiation therapy using established magnetic resonance imaging technology for image guidance. Both devices rely on the same split magnet design to create an area of reduced X-ray attenuation for the treatment beam. Both devices use the same specifically designed software systems for treatment planning and delivery.

The similarities and differences in key device characteristics and performance specifications of the current and predicate Elekta Unity device configuration are noted in the table below:

Technological Characteristics Comparison		Unity (Subject Device)	Unity (K192482)
Radiation Source / Beam	7MV Bremsstrahlung X- Rays produced by Linear Accelerator	✓	✓
Method of IMRT	MLC based cone-beam delivery	✓	✓
Collimation	Field shaping, Multi Leaf Collimator (MLC)	✓	✓
MLC material	Tungsten Alloy	✓	✓
Number of leaves	80 leaf pairs	✓	✓
Range of MLC collimated beam size @ isocenter	0.5 cm x 0.5 cm to 57.4 cm x 22 cm	✓	✓
Gantry	Ring Gantry, collision with patient not possible	✓	✓
Radiation Head Shielding	Lead, Tungsten Alloy, and Steel shielding	✓	✓
Source control mechanism	Dual channel dose monitoring system	✓	✓
Radiation Transmission through head	0.2% of the primary beam	✓	✓
Isocenter distance	143.5 cm	✓	✓
Isocenter accuracy (Radius)	0.5mm	✓	✓
Max Dose Rate	Clinical use: 450 cG/min at isocentre at Dmax for a 10 cm x 10 cm field (500 MU/min @ isocentre measured at Dmax)	ü	✓
Static Dose Accuracy	>95% of points passing 3%/3mm in the high dose, low gradient region >95% passing 5mm/5% for low dose, high gradient points 1% agreement for output factors	✓	✓
Motion synchronized treatment	No – Manual interrupt only	✓	✓
Patient table degrees of freedom	2 (vertical & longitudinal) – positional corrections are made using the online adaptive planning interface of the treatment planning system	✓	✓
Integrated imaging for planning, positioning, gating	Magnetic resonance imaging system – for planning, positioning and motion monitoring during treatment	✓	✓
MR Physical Characteristics	Bore Diameter: 700 mm Diameter Spherical Volume: 500 mm x 500 mm x 450 mm	✓	✓
MRI Frequency Field Strength Field of View Field Homogeneity Field Stability	64 MHz 1.5T Up to 500 mm Sequence dependent ≤ 2 ppm measured over 50 cm x 50 cm x 45 cm volume ≤ 0.1 ppm/hour	✓	✓
3D Imaging Volumes (cm) 3D Imaging Resolution (cm)	RL x AP x HF Min 0.5 x 0.5 x 0.8 Max 56 x 56 x 40 (Anterior coil dependent) Min 0.01 x 0.01 x 0.1 Max 0.875 x 0.875 x 1	✓	✓

Technological Characteristics Comparison		Unity (Subject Device)	Unity (K192482)
2D Imaging Planes (cm) 2D Imaging Resolution (mm)	AP x HF Min 0.5 x 0.5 Max 56 x 56 Resolution selectable: 0.011 x 0.011 mm (min) 8.75 x 8.75 mm (max) Slice thickness selectable: 0.01 mm (min); 705 mm (max) <=1 mm over 20 cm FOV (Guaranteed)	✓	✓
Geometric Accuracy	<=2 mm over 34 cm FOV (Guaranteed) <=2 mm over 42 cm FOV (Typical)		
Signal to Noise	120		
Diffusion Weighted Imaging (DWI)	Diffusion Weighted Images can be imported from an alternative magnetic resonance imaging device for Off-line review.	✓	✓
Treatment Planning and Delivery System Dose Output Modelling Dose Display	GPU-based Monte Carlo dose calculation algorithm (GPUMCD) using the compatible Elekta MONACO treatment planning system Dose output modelled with monitor units Display of Linac delivery parameters	✓	✓
Compressed Sense (CS-SENSE) imaging option	Additional imaging options for diagnosis, treatment planning, and position verification.	✓	X
Breath-Hold imaging option		✓	X
3D Vane XD imaging option		✓	X
Minimum Room Dimensions Environment Line Voltage Ambient Room Temp. Relative Humidity Power Distribution Isolation	(H/L/W) 3.25 m x 6.7 m x 6.7 m 480V Treatment room: 18 to 22 °C (65 °F to 72 °F) Treatment room: 40 to 70%, non- condensing Transformer	✓	✓

VIII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Design verification and performance testing were carried out in accordance with design controls of 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 FDA guidance[1].

Non-clinical testing was performed to evaluate device performance and functionality against design and risk management requirements at sub-system, integration and system levels. Software verification testing was conducted and documented in accordance with FDA guidance[2] for devices that pose a major level of concern (Class C per IEC 62304).

[1] Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices – Guidance for Industry and Food and Drug Administration Staff, November 2016

[2] Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and Food and Drug Administration Staff, May 2005

Basic safety and essential performance have been satisfied through conformance with device-specific recognized consensus standards, as well as the general and collateral safety and essential performance standards for medical devices listed below.

Standard No.	Standard Title
ISO 14971	Medical Devices – Application of risk management to medical devices
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-1	Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
IEC 60601-2-33	Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
IEC 61217	Radiotherapy equipment - Coordinates, movements and scales
IEC 60976	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 62304	Medical device software – Software life-cycle processes
IEC 62366-1	Medical devices - Application of usability engineering to medical devices
ANSI IEEE C63.18	Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

IX. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that Elekta Unity is as safe and effective and performs as well as the predicate device Elekta Unity.

X. SUBSTANTIAL EQUIVALENCE CONCLUSION

Elekta Unity is substantially equivalent (SE) to the predicate device, Elekta Unity (K192482). The intended use and indications for use are identical to the predicate device and the principles of operation remain unchanged.

The technological characteristics are substantially equivalent to the predicate device; the differences in imaging functionality between the two devices do not affect the fundamental scientific technology or raise different questions of safety or effectiveness of the device. The device safety and performance have been addressed by non-clinical testing in conformance with predetermined performance criteria, FDA guidance, and recognized consensus standards.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that Elekta Unity meets the established safety and performance criteria and is substantially equivalent to the predicate device.