



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

February 23, 2023

Re: K223209  
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: January 26, 2023  
Received: January 26, 2023

Dear 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/pmnmn.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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S  
Digitally signed by Lora D. Weidner -S  
Date: 2023.02.23 14:40:52 -05'00'

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

510(k) Number (if known)

K223209

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)****I. SUBMITTER**

Elekta Solutions AB  
Kungstengsgatan 18 Box 7593  
Stockholm, SE SE10393

Contact: Melinda Smith, MS, RAC, CBA  
[Melinda.Smith@elekta.com](mailto:Melinda.Smith@elekta.com)

Establishment Registration #: 3015232217

510(k) Number: K223209

Date Prepared: 13 October 2022

**II. DEVICE**

Trade Name: Elekta Unity MR Linac

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 (K212114)

**IV. 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).

**V. 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.



## **VI. 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 motion monitoring with manual interrupt previously cleared with predicate Unity devices, the subject device Elekta Unity has added the following motion management strategies:

- Anatomic Position Monitoring (APM) with Manual interrupt (also referred to as True Tracking as it 'tracks' in 3D and enables the system to gate using the 3D position of the anatomy's motion)
- APM with Anatomic Tolerance Check (ATC)
- Adaptive Therapy with optional Baseline Shift (BLS) Recovery.

These modifications are not contained solely within the Elekta Unity Device, as the full clinical benefit is achieved with interoperability of Unity, Monaco RTP, and MOSAIQ OIS.

## **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 (K212114)
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	0.5cm x 0.5cm to 57.4cm x 22cm	✓	✓
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)	0.5 mm	✓	✓
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)	✓	✓
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 Management Strategies	Motion monitoring with manual interrupt	✓	✓
	Anatomical Position Monitoring (APM) with manual interrupt	✓	X
	APM with ATC (Anatomical Tolerance Check)	✓	X
	Adaptive Therapy with optional BLS (Baseline Shift) Recovery	✓	X
End-to-End Gating Latency	[-200 to +200 ms] (radiation off) and [-200 to +280 ms] (radiation on) for ATC for free-breathing respiratory motion treatment techniques	✓	X
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	64 MHz 1.5T Up to 500 mm Sequence dependent ≤ 2 ppm measured over 50 cm x 50 cm x 45 cm volume	✓	✓

Technological Characteristics Comparison		Unity (Subject Device)	Unity (K212114)
Field Stability	≤ 0.1 ppm/hour		
3D Imaging Volumes (cm) 3D Imaging Resolution (cm)	RL x AP x HF: 0.5 x 0.5 x 0.8 (min) / 56 x 56 x 40 (max) (Anterior coil dependent) 0.01 x 0.01 x 0.1 (min) / 0.875 x 0.875 x 1 (max)	✓	✓
2D Imaging Planes (cm) 2D Imaging Resolution (mm)	AP x HF: 0.5 x 0.5 (min) / 56 x 56 (max) 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	✓	✓



## VIII. SUMMARY OF PERFORMANCE 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<sup>1</sup>.

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<sup>2</sup> 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 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
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

## IX. SUMMARY OF PERFORMANCE 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.

<sup>1</sup> Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices – Guidance for Industry and Food and Drug Administration Staff, November 2016

<sup>2</sup> Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and Food and Drug Administration Staff, May 2005





**X. SUBSTANTIAL EQUIVALENCE CONCLUSION**

Elekta Unity is substantially equivalent (SE) to the predicate device, Elekta Unity (K212114). 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 additional motion management strategies 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 pre-determined 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.