Elekta Limited
% Mr. Nicholas Power
RA Manager
Fleming Way
CRAWLEY, WEST SUSSEX, RH10 9RR
GREAT BRITAIN

December 4, 2018

Re: K182076
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
Dated: October 29, 2018
Received: November 2, 2018

Dear Mr. Power:

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,

Michael D. O'Hara For

Robert A. 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)*
182076

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 the 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. Images provide information that 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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K182076

510(k) SUMMARY

as required by 21 CFR 807.92

Date of preparation:	**July 26, 2018**
Submitted by:	Elekta Limited Linac House, Fleming Way, Crawley, West Sussex RH10 9RR, United Kingdom Telephone: +44 (0)1293 544422 Fax: +44 (0)1293 654321
Contact name:	Nicholas Power
Name of Device:	Elekta MR-Linac
Trade / Proprietary Name:	Elekta Unity
Common or Usual Name:	Image-Guided Radiation Therapy System
Classification Name:	Medical charged-particle radiation therapy system, 21CFR 892.5050
Product Code:	IYE, LNH
Device classification name:	Accelerator, Linear, Medical
Predicate Device:	ViewRay (MRIdian) Linac System, K170751

Product 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). Elekta Unity consists of a gantry-mounted 7MV linear accelerator sub-system which rotates around a 1.5T Magnetic Resonance Imaging (MRI) sub-system and a Patient Positioning Sub-system (PPS). It is controlled by dedicated system software, which incorporates patient positioning, imaging, and treatment delivery functions, and it is designed for use in conjunction with approved compatible Oncology Information and Treatment Planning systems. 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.

Intended 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.

Indications for Use Statement:

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 MRI 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. Images provide information that may assist the therapy planning, patient positioning and treatment delivery related to radiation oncology.

Substantial Equivalence:

Elekta Unity is substantially equivalent (SE) to the predicate device, the ViewRay (MRIdian) Linac System (K170751) in intended use and indications for use, principles of operation, technological characteristics and labeling. The differences between the two devices have been addressed by non-clinical testing in conformance with predetermined performance criteria and recognised consensus standards.

Summary of Technological Characteristics:

Both devices are designed specifically to facilitate IGRT; they rely on established medical linear accelerator (linac) technology to deliver comparable photon energies and dose rates for targeted external beam radiation therapy, using established magnetic resonance imaging (MRI) technology for image guidance, and specifically designed software systems for treatment planning and delivery. Both devices incorporate a split magnet design to create an area of reduced X-ray attenuation for the treatment beam. Elekta Unity incorporates a 1.5T MRI sub-system as compared to the predicate's 0.345T MRI sub-system.

Key device characteristics and performance specifications of the Elekta Unity and the predicate device are noted in the table below:

Device Characteristic	**Cleared Device (K170751)**	**Elekta Unity**	**Comparison**
Radiation Source / Beam	6 MV Bremsstrahlung X- Rays Produced by Linear Accelerator	7MV Bremsstrahlung X- Rays Produced by Linear Accelerator	Substantially equivalent (SE) energy source and output
Method of IMRT	MLC based cone-beam delivery	MLC based cone-beam delivery	Same
Collimation	Field shaping, Multi Leaf Collimator (MLC)	Field shaping, Multi Leaf Collimator (MLC)	SE MLC specifications; IEC 60601-2-1 compliant
MLC material	Tungsten Alloy	Tungsten Alloy	
Number of leaves	34 leaf pairs upper stack, 35 leaf pairs lower stack	80 leaf pairs	
Range of MLC collimated beam size @ isocenter	0.415 cm x 0.2 cm to 27.4 cm x 24.1 cm	0.5 cm x 0.5 cm to 57.4 cm x 22 cm	
Gantry	Ring Gantry, collision with patient not possible	Ring Gantry, collision with patient not possible	Same

Device Characteristic	**Cleared Device (K170751)**	**Elekta Unity**	**Comparison**
Radiation Head Shielding	Lead, Tungsten Alloy, and Steel shielding	Lead, Tungsten Alloy, and Steel shielding	Same
Source control mechanism	Redundant ion chambers and dose monitoring cards	Dual channel dose monitoring system	SE mechanisms; IEC 60601-2-1 compliant
Radiation Transmission through head	Less than 0.1% of the primary beam	0.2% of the primary beam	SE specification; IEC 60601-2-1 compliant
Isocenter distance	90 cm	143.5 cm	SE; no impact on dose accuracy
Isocenter accuracy (Radius)	0.5mm	0.5mm	Same
Max Dose Rate	600 cGy/min at Dmax at a 90 cm isocenter for a 10 cm x 10 cm field	Clinical use: 450 cG/min at isocentre at Dmax for a 10 cm x 10 cm field (500 MU/min @ isocentre measured at Dmax)	SE dose rate at isocenter
Static Dose Accuracy	90% of the points evaluated in a treatment volume pass a relative gamma criteria of 3%/3mm and a high dose, low gradient absolute point measurement is within 5% of the planned dose (per AAPM TG 119 based on the recommendations of Palta et al.).	>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.	SE dose accuracy specification
Motion synchronized treatment	Yes	No – Manual interrupt only	No automatic gating function in Unity
Patient table degrees of freedom	3 translational	2 (vertical & longitudinal) – positional corrections are made using the online adaptive planning interface of the treatment planning system	SE; Position accuracy is compliant with IEC 60601-2-1
Integrated imaging for planning, positioning, gating	Magnetic resonance imaging system	Magnetic resonance imaging system – for planning, positioning and motion monitoring during treatment	SE; No automatic gating function in Unity
MR Physical Characteristics Bore Diameter Diameter Spherical Volume	 700 mm 500 mm	 700 mm 500mm x 500mm x 450mm	SE physical specifications

Device Characteristic	**Cleared Device (K170751)**	**Elekta Unity**	**Comparison**
MRI Frequency	14.7 MHz	64 MHz	SE MRI system; IEC 60601-2-33 compliant
Field Strength	0.345 T	1.5T	
Field of View	500 mm	Up to 500 mm Sequence dependent	The effects of 1.5T magnetic field on dose distribution are accounted for in the treatment planning system
Field Homogeneity	< 25 ppm measured over 45 cm diameter spherical volume	≤ 2 ppm measured over 50 cm x 50 cm x 45 cm volume	
Field Stability	≤ 0.1 ppm/hr	≤ 0.1 ppm/hr	
3D Imaging Volumes (cm)	RL x AP x HF Min 20 x 27 x 29 Max 54 x 48 x 54	RL x AP x HF Min 0.5 x 0.5 x 0.8 Max 56 x 56 x 40 (Anterior coil dependent)	SE imaging volumes and geometric accuracy; higher resolution and signal to noise performance with 1.5T MRI
3D Imaging Resolution (cm)	Min 0.075 x 0.075 x 0.15 Max 0.3 x 0.3 x 0.3	Min 0.01 x 0.01 x 0.1 Max 0.875 x 0.875 x 1	
2D Imaging Planes (cm)	AP x HF Min. 27 x 27 Max 45 x 35	AP x HF Min 0.5 x 0.5 Max 56 x 56	
2D Imaging Resolution (mm)	0.35 x 0.35 5,7, or 10	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)	
Geometric Accuracy	1 mm over 20 cm FOV 2 mm over 35 cm FOV	<=1 mm over 20 cm FOV (Guaranteed) <=2 mm over 34 cm FOV (Guaranteed) <=2 mm over 42 cm FOV (Typical)	
Signal to Noise	30	120	
Treatment Planning and Delivery System Dose Algorithm	Monte Carlo Dose Computation Radiation Source Model for Bremsstrahlung X-Rays	GPU-based Monte Carlo dose calculation algorithm (GPUMCD) using the compatible Elekta MONACO treatment planning system	SE dose calculation methods
Dose Output Modelling	Dose output modelled with monitor units	Dose output modelled with monitor units	
Dose Display	Display of Linac delivery parameters	Display of Linac delivery parameters	

Device Characteristic	**Cleared Device (K170751)**	**Elekta Unity**	**Comparison**
Minimum Room Dimensions (H/L/W)	2.9 m x 7.6 m x 5.9 m	3.25 m x 6.7 m x 6.7 m	SE operating environment
Environment Line Voltage	480V	480V	
Ambient Room Temp.	65 °F to 72 °F	Treatment room: 18 to 22 °C (65 °F to 72 °F)	
Relative Humidity	40 to 60%	Treatment room: 40 to 70%, non-condensing.	
Power Distribution Isolation	Transformer	Transformer	

Summary of performance testing (non-clinical):

Design verification and performance testing were carried out 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 presented below. 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'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.

Standard Title	**Standard No.**
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1
Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV	IEC 60601-2-1
Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis	IEC 60601-2-33
Radiotherapy equipment - Coordinates, movements and scales	IEC 61217
Medical electrical equipment. Medical electron accelerators. Functional performance characteristics	IEC 60976
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic	IEC 60601-1-2
Medical devices - Application of usability engineering to medical devices	IEC 62366-1
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC 60601-1-6
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO 10993-1

Validation and usability testing of the integrated system was performed in accordance with FDA guidance on human factors and usability engineering under clinically representative conditions by competent and professionally qualified personnel. The results from verification and validation testing demonstrate device conformance to stated design specifications and standards.

Conclusion

The results of verification, validation and safety standards testing demonstrate that Elekta Unity fulfills the established safety and performance criteria and it is substantially equivalent to the predicate device.