MagnetTx Oncology Solutions Ltd.
℅ Mr. Michael Cook
Lead Regulatory Engineer
9505 41 Avenue NW
Edmonton, Alberta T6E 5X7
CANADA

May 4, 2022

Re: K213526
Trade/Device Name: Aurora-RT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: April 1, 2022
Received: April 4, 2022

Dear Mr. Cook:

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,

Julie Sullivan, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy
OHT8: Office of 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)*
K213526

Device Name
Aurora-RT

Indications for Use *(Describe)*
The Aurora-RT, with magnetic resonance imaging capabilities, is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

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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5 510(K) SUMMARY K213526

The following information is provided for Aurora-RT in accordance with 21 CFR 807.92.

5.1 Submitter Information

Submitter	MagnetTx Oncology Solutions Ltd. 9505 41 Avenue NW Edmonton, Alberta T6E 5X7 Canada Telephone: 587-458-1162
Primary Contact	Michael Cook Lead Regulatory Engineer Telephone: 587-458-1162 michael.cook@magnettx.com
Secondary Contact	Brad Murray Chief Technology Officer Telephone: 780-886-6728 brad.murray@magnettx.com
Date Summary Prepared	March 31, 2022

5.2 Device Identification

Trade Name	Aurora-RT
Common Name	Medical Linear Accelerator with Magnetic Resonance Image Guidance
Classification Name	Accelerator, Linear, Medical; System, Nuclear Magnetic Resonance Imaging
Classification Panel	Radiology
Regulation	21 CFR 892.5050, 21 CFR 892.1000
Device Class	Class II
Product Code	IYE, LNH

5.3 Predicate Device

ViewRay MRIdian Linac System with 138-leaf Collimator (K170751)

5.4 Device Description

Aurora-RT is a medical device for image-guided radiation therapy (IGRT) that combines magnetic resonance imaging (MRI) with radiotherapy technology. It combines a 6 MV medical linear accelerator (Linac) and 0.5 T cryogenless superconducting MRI system mounted in a rotating gantry frame. The MR imaging capability is utilized for positioning the patient at the start of radiation therapy in place of computed tomography (CT) imaging that is commonly used in radiation therapy. MR imaging offers superior soft tissue contrast compared to CT and does not utilize ionizing radiation as with CT images.

5.5 Intended Use

The Aurora-RT, with magnetic resonance imaging capabilities, is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

5.6 Indications for Use

The Aurora-RT, with magnetic resonance imaging capabilities, is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

5.7 Substantial Equivalence

The Aurora-RT is substantially equivalent to the predicate device, the ViewRay MRIdian Linac System with 138-leaf Collimator (K170751), based on the intended use, indications for use, technological comparison, and performance data.

5.8 Technological Characteristics

The Aurora-RT uses the same fundamental technology as that of the ViewRay MRIdian Linac System: they are both Linac-MR devices that combine a 6 MV Linac and MRI system. The Aurora-RT and ViewRay MRIdian Linac System both use the same 6 MV photon energy for treatment delivery and the MRI systems have substantially equivalent magnetic fields (0.5 T for Aurora-RT vs 0.345 T for ViewRay MRIdian Linac System). The Aurora-RT, like the ViewRay MRIdian Linac System, provides intensity-modulated radiotherapy (IMRT) and is intended to be used by radiation oncology professionals.

The main technological difference between the two devices is that Aurora-RT utilizes a rotating biplanar magnet, which puts the main magnetic field parallel to the radiation beam. The ViewRay MRIdian Linac System uses a stationary Helmholtz-type magnet where the magnetic field is perpendicular to the radiation beam.

The main technological characteristics of Aurora-RT are compared to the ViewRay MRIdian Linac System in the table below, with the technological characteristics organized by the two main functionalities of the devices: Linac and MRI.

Parameter	**Proposed Device: Aurora-RT**	**Predicate Device: ViewRay MRIdian Linac System (K170751)**
Linac		
Radiation Source	6 MV Linear Accelerator	6 MV Linear Accelerator
Beam	6 MV Bremsstrahlung X-Rays produced by Linear Accelerator	6 MV Bremsstrahlung X-Rays produced by Linear Accelerator
Max Dose Rate	600 cGy/min at Dmax at 120 cm isocenter for a 10 x 10 cm^2 field	600 cGy/min at Dmax at 90 cm isocenter for a 10 x 10 cm^2 field

Parameter	Proposed Device: Aurora-RT	Predicate Device: ViewRay MRIdian Linac System (K170751)
Static Dose Accuracy	90% of the points evaluated in a treatment volume pass a gamma criteria of 3%/3mm.	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.).
Collimation	Multi-Leaf Collimator (MLC) and 2 independent Y jaws	Multi-Leaf Collimator (MLC) in two banks
Projected MLC Leaf Width	0.475 cm	0.83 cm
Number of MLC Leaves	120 (single bank)	138 (68 in upper bank, 70 in lower bank)
MLC Material	Tungsten Alloy	Tungsten Alloy
Isocenter Distance	120 cm	90 cm
Isocenter Accuracy	1 mm diameter	1 mm diameter
Radiation Head Shielding	Lead and Steel Shielding	Lead, Tungsten Alloy, and Steel Shielding
Dosimetry System	Redundant ion chambers and dosimetry circuits	Redundant ion chambers and dose monitoring cards
Radiation Transmission through the head	Less than 0.1% of the primary beam	Less than 0.1% of the primary beam
Method of IMRT	Sliding Window and Step and Shoot dynamic MLC	MLC based cone-beam delivery
Gantry	Rotating Gantry with front and back bearings	Ring Gantry, collision with patient not possible
Patient table degrees of freedom	3 translational	3 translational
Motion Synchronized Treatment	Not applicable	Yes (Gating utilized)
Linac Configuration	Rotates in tandem with magnet (fixed with respect to magnet)	Rotates about stationary magnet

Parameter	Proposed Device: Aurora-RT	Predicate Device: ViewRay MRIdian Linac System (K170751)
Treatment Planning System	Treatment planning with existing cleared TPS	Treatment Planning and Delivery System (K102915 ViewRay) Monte Carlo Dose Computation Radiation Source Model for Bremsstrahlung X-Rays
Dose Output Modeling	Dose output modeled with monitor units	Dose output modeled with monitor units
Dose Display	Display of Linac delivery parameters	Display of Linac delivery parameters
MRI		
Integrated imaging	Magnetic Resonance Imaging System (for positioning only prior to treatment start)	Magnetic Resonance Imaging System (for planning, positioning, and gating)
MR Configuration	Rotating biplanar magnet (open magnet design)	Stationary Helmholtz-type magnet
Magnetic field/Linac Beam alignment	Parallel	Perpendicular
Bore Diameter	600 mm x 1100 mm (600 mm pole-to-pole spacing) ellipse defined by pole plates and front bearing	700 mm circle
Diameter Spherical Volume (DSV)	400 mm	500 mm
MRI Frequency	20.6 MHz	14.7 MHz
Field Strength	0.5 T	0.345 T
Field of View	400 mm	500 mm
Field Homogeneity	< 38 ppm (VRMS) measured over 400 mm DSV	< 25 ppm measured over 450 mm DSV
Field Stability Control	Active control	Persistent superconducting magnet
Field Stability	< 0.1 ppm/min under active power supply control	< 0.1 ppm/hour
3D Imaging Volumes [cm]	RL x AP x HF Min 10 x 10 x 4 Max 40 x 40 x 30	RL x AP x HF Min 20 x 27 x 29 Max 54 x 48 x 54
3D Imaging Resolution [cm]	RL x AP x HF Min 0.04 x 0.04 x 0.04 Max 0.16 x 0.16 x 0.27	RL x AP x HF Min 0.075 x 0.075 x 0.15 Max 0.3 x 0.3 x 0.3

Parameter	Proposed Device: Aurora-RT	Predicate Device: ViewRay MRIdian Linac System (K170751)
Geometric Accuracy	< 1.0 mm V_{RMS} over 20 cm DSV	2 mm over 35 cm FOV 1 mm over 20 cm FOV
Signal to Noise Ratio	> 30	30
Imaging Dose per treatment	None	None

5.9 Summary of Performance Testing

Comprehensive performance testing has shown that the few differences in technological characteristics between Aurora-RT and the predicate device do not affect the safety and effectiveness of Aurora-RT for its intended use. Design control procedures applied to the development of Aurora-RT, including verification and validation testing, are in compliance with *21 CFR 820 FDA Quality System Regulation*, *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes*, and *ISO 14971 Medical devices – Application of risk management to medical devices*.

The performed testing demonstrated conformance to design requirements and recognized consensus standards and ensured all identified risks and hazards were mitigated.

Software verification testing was conducted and documented in accordance with the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for devices that pose a major level of concern.

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. The Aurora-RT has been found to conform to the medical device safety standards presented in the table below.

Standard No.	Edition (Year)	Title
IEC 60601-1	3.1 (2012)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	4 (2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6	3.1 (2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-1	3.1 (2014)	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

Standard No.	Edition (Year)	Title
IEC 60601-2-33	3.2 (2015)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 61217	2 (2011)	Radiotherapy equipment - Coordinates, movements and scales
IEC 62304	1.1 (2015)	Medical device software - Software life cycle processes
IEC 62366-1	1 (2015)	Medical devices - Part 1: Application of usability engineering to medical devices

5.10 Conclusion

Verification and validation testing demonstrated that the Aurora-RT met established standards and design requirements. The differences between the Aurora-RT and the predicate device do not raise any new concerns of safety or effectiveness and do not negatively impact the device's performance for its intended use. Therefore, the Aurora-RT is substantially equivalent to the predicate device.