

MAGNETTX- AURORA RT RECEIVES FDA CLEARANCE

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Aurora RT

MagnetTX announces FDA cleared Aurora RT. Innovative radiation therapy system that combines MRI and Linear accelerator to help cancer patients.

Online PR News – 07-May-2022 – May 4, 2022 Edmonton Alberta –
Announcing: MagnetTx Aurora-RT™ Is FDA Cleared

FOR IMMEDIATE RELEASE:

The FDA has provided clearance to MagnetTx Oncology Solutions for its one-of-a-kind linear accelerator with MR guidance (LINAC-MR), Aurora-RT. May 2022 (Maryland) — On May 4, 2022, MagnetTx received clearance from the FDA for its Aurora-RT™ LINAC-MR. Now, the revolutionary device can be sold throughout the U.S.

In November 2021, MagnetTx submitted its application to the Food and Drug Administration's (FDA) Center for Devices and Radiological Health, which then processed the company's required documentation and evidence, reviewed it for regulatory consideration and archived it.

The FDA regulates the sale of medical device products in the U.S. and monitors the safety of all regulated medical products. A medical device that's been FDA cleared means it's undergone a 510(k) submission. With clearance, the FDA is allowing MagnetTx's device to the market through the 510(k) process based on substantial equivalence to a legally marketed predicate device.

"This marketing clearance is the path forward in reaching our goals of providing cost-effective radiation treatments with MRI guidance. Aurora-RT is the next-generation treatment modality that will expand the MRI-guided and overall radiotherapy market significantly," said Mike Cogswell, MagnetTx President & CEO. "Transitioning MagnetTx from research into a commercial company will be an exciting time for us! With the launch of our "Northern Lights Clinical Consortium," we're confident that we'll continue to add to the critical data that's been established by the early technologies."

"Aurora-RT is a radical shift in design, with a rotating bi-planar magnet that brings numerous advantages including minimal impact on dosimetry and the opportunity to deliver isocentric treatments to off-center disease, such as tangential breast," noted MagnetTx founder Brad Murray. "These advantages will push the utilization of MRI-guided therapy from a specialty device to one that can be used every day with all patients," added MagnetTx founder Gino Fallone.

The innovative Aurora-RT LINAC-MR combines high-quality .5T open system with a 6 MV linear accelerator. This designs make the Aurora-RT perfectly suited for radiotherapy — and unlike anything on the market for cancer treatment today.

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MagnetTx Oncology Solutions, Ltd. Is a Canadian-based company that develops global pioneering technology. We've combined a linear accelerator (Linac), magnetic resonance imaging (MRI) to deliver radiotherapy to cancer patients. Our goal is to substantially reduce radiation treatment margins and improve cancer patient outcomes with fewer adverse side effects. Our first device is the groundbreaking Aurora-RT™.

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