Press release: January 16, 2026

Elekta receives FDA 510(k) clearance for Elekta Evo linear accelerator

ATLANTA – Elekta (EKTA-B.ST) announced that its Elekta Evo* CT-Linac has today received 510(k) clearance from the U.S. Food and Drug Administration (FDA). This milestone makes the system available to radiation oncology professionals in the United States.

When delivering radiation therapy, clinicians require high-quality images that allow them to identify tumors and organs-at-risk. Evo addresses this with Iris® high-definition, AI-enhanced imaging, which allows physicians to see target areas and critical structures for every fraction with greater clarity. In Europe and other countries, Elekta Evo continues to gain traction, setting new benchmarks in radiation therapy as more clinics adopt its innovative treatment capabilities.

Ardie Ermers, Executive Vice President, Region Americas, says: “Securing FDA clearance for Elekta Evo is a pivotal step in our commitment to the U.S. market. With Evo, we are empowering American clinics to adopt the latest advances in radiation therapy, delivering more personalized, precise care for their patients. Our strategy is to ensure that every provider, regardless of size or location, can access innovative solutions that improve outcomes and operational efficiency. Evo’s versatility and AI-driven imaging set a new standard for cancer care in the United States.”

Eenas Omari, PhD, a member of the radiation oncology team at Medical College of Wisconsin, which was involved in the development of Iris, says: "Iris provides enhanced image quality. The reduction in artifacts and improved soft tissue contrast not only enhance daily image guidance for precise patient positioning but also allows us to see anatomical changes with greater confidence. This capability maximizes targeting precision and truly personalizes care for each patient."

Unlike conventional cone-beam CT imaging, Evo uses AI to reduce scatter and enhance image reconstruction. This leads to clearer images and helps clinicians see structures more accurately, which supports better decision-making. Iris’s AI-enhanced image quality has been designed to allow for easy upgrading on existing Elekta linacs (dependent on specific linac version; please contact Elekta to learn more).

To learn more about Elekta Evo, visit the Elekta Evo webpage.

**Elekta Evo has CE mark and U.S. FDA 510(k) clearance. Not available in all markets.*

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About Elekta
As a leader in precision radiation therapy, Elekta is committed to ensuring every patient has access to the best cancer care possible. We openly collaborate with customers to advance sustainable, outcome-driven and cost-efficient solutions to meet evolving patient needs, improve lives and bring hope to everyone dealing with cancer. To us, it's personal, and our global team of 4,500 employees combine passion, science, and imagination to profoundly change cancer care. We don’t just build technology, we build hope. Elekta is headquartered in Stockholm, Sweden, with offices in more than 40 countries and listed on Nasdaq Stockholm. For more information, visit elekta.com.