Elekta wins FDA approval for diffusion-weighted images

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Elekta (STO:EKTA B) today announced that it received FDA 510(k) premarket notification for its diffusion-weighted MR images from the Elekta Unity.

The clearance allows the images to be interpreted by a trained physician. With the new FDA clearance, the system can be used for the biologic assessment of tumor response during therapy.

Diffusion-weighted MR images (DWI) map the diffusion of water molecules at the cellular level and can be processed to generate an apparent diffusion coefficient (ADC). The company says ADC changes can provide insight into tumor response that could help personalize radiation therapy.

“One of the goals for Elekta Unity was to develop an MR-guided radiation therapy system that not only treats patients with unparalleled anatomic personalization but could also incorporate the individuals’s response to their treatment,” president and CEO Richard Hausmann said in a news release. “This new functionality has excited early adopters of Unity. It allows us to assess biologic changes within the tumor, which may occur earlier than anatomic changes. This will improve clinicians’s ability to deliver the right dose to the right part of the tumor based on this new biological marker.”

The Elekta Unity system features a high-field 1.5 Tesla MRI scanner and a linear accelerator with integrated real-time dose planning software for target monitoring. The company says it has the ability to reshape doses based on daily changes in shape, size and position of the tumor and surrounding healthy anatomy.