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Korea's NeuroXT receives US FDA 510(k) clearance for AI software supporting prognostic assessment in Mild Cognitive Impairment

October 21, 2026 | News

NeuroXT Inc. to advance US commercialisation and adoption by healthcare institutions following FDA 510(k) clearance



South Korea-based startup NeuroXT Inc., a medical device manufacturer, has announced that NEXT-Cue, its AI-based Software as a Medical Device (SaMD) supporting prognostic assessment in patients with mild cognitive impairment (MCI), has received 510(k) clearance from the US Food and Drug Administration (FDA) as a Class II medical device.

NEXT-Cue supports clinicians in assessing patients with MCI who are being evaluated for progression to Alzheimer's dementia within five years. By integrating brain MRI images, demographic information, and cognitive assessment data, it provides supplementary information to support clinical assessment and individualised patient management planning.

"Receiving FDA 510(k) clearance marks an important milestone in NeuroXT's entry into the US healthcare market," said Joon-Kyung Seong, CEO of NeuroXT Inc. "Starting with NEXT-Cue, we plan to establish real-world clinical use cases at leading healthcare institutions across the United States and accelerate our commercialisation efforts, with the broader goal of contributing to earlier diagnosis and appropriate treatment of Alzheimer's disease."

NeuroXT Inc. is also pursuing regulatory authorisation for NEXT-Cue from the Ministry of Food and Drug Safety (MFDS) in the Republic of Korea and plans to begin commercialisation in the Korean market early next year.