

Korean startup Neurophet secures US FDA 510(k) clearance for multiple sclerosis analysis with 'Neurophet AQUA'

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Accelerating global expansion with cutting-edge technology targeting multiple sclerosis, a prevalent condition in North America and Europe



Neurophet, an artificial intelligence (AI) solution company for brain disease, has announced that its brain MRI analysis software 'Neurophet AQUA', has obtained 510(k) clearance from US Food and Drug Administration (FDA) for its newly integrated multiple sclerosis (MS) analysis functionality.

The initial clearance, secured in May last year, authorised brain atrophy analysis using T1-weighted images derived from MRI scans, specifically targeting neurodegeneration conditions. The latest clearance extends the software's capabilities, incorporating advanced analysis of MS and white matter hyperintensities (WMH) using T2-FLAIR images.

Neurophet AQUA analyses MRI (magnetic resonance images) with AI technology to analyse brain atrophy and WMH observed in neurodegenerative diseases such as Alzheimer's disease. It provides rapid segmentation and analysis of brain images across all demographics, delivering results within just five minutes.

The software's MS analysis technology quantifies lesions and structural changes, enabling precise measurement of lesion count, volume, and progression. Notably, it delivers robust segmentation across both 2D and 3D imaging methods of T2-FLAIR MRI at 1.5T and 3.0T, while also enabling volumetric analysis of brain regions without requiring 3D T1 imaging.

MS is a demyelinating autoimmune disease of the central nervous system, affecting the brain, spinal cord, and optic nerves. Characterized by inflammatory and neurodegenerative damage, the condition predominantly impacts individuals aged 20 to 40, with a higher prevalence among women. MS is most common among Caucasians inNorth America and Europe, while its occurrence is relatively lower among Asian and African Americans.