Oxford Brain Diagnostics has been granted FDA Clearance for its novel MRI Software – CDM Insights, marking a key advancement in assessing neurodegeneration for patients

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Oxford Brain Diagnostics is proud to announce that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for CDM Insights. Powered by our pioneering Cortical Disarray Measurement (CDM®) technology, CDM Insights provides a new and deeper understanding of the brain's microstructure from MRI scans. The FDA cleared CDM Insights software enables clinical brain assessment by trained healthcare practitioners evaluating patients with neurodegenerative disorders such as Alzheimer's disease.

"We are setting the new standard for precise measurement of cortical microstructure. This is a significant step on our global mission of 'Rethinking Brain Health'" said Dr Steven Chance, CEO and Co-Founder of Oxford Brain Diagnostics. "Our technology empowers clinicians with the tools they need to detect subtle brain changes and to diagnose with confidence at an early stage. These insights also help patients gain a better understanding of the changes happening in their brains, addressing the uncertainty often experienced with the early signs of Alzheimer's disease. Ultimately, this enables providers and carers to understand patient brain structure changes prior to symptom progression and improve patient outcomes."

CDM Insights includes new measurements of microstructure and cortical thickness previously not available on the US market, supporting clinicians to open the gateway into early detection of neurodegeneration in patients. As part of our standard delivery, the product will also provide macrostructural measures.

This all-in-one solution is cloud native, non-invasive and monitors brain changes in patients across the multiple stages of adult life. CDM Insights processes clinical MRI scan data from both 1.5T and 3T scanners and delivers outputs in the form of images and numerical values, usually presented as percentiles of a normative population distribution. CDM Insights will be available to all US healthcare facilities, intended for use by neurologists, radiologists, and other trained healthcare practitioners familiar with the post-processing of magnetic resonance images.

CDM Insights is not intended to be used in isolation for diagnosis or treatment decisions. The physician retains the ultimate responsibility for making any final diagnosis and treatment decisions.

To learn more, please contact
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About Oxford Brain Diagnostics Ltd - Oxford Brain Diagnostics Ltd is rethinking how brain health is assessed and managed. Founded in neuropathological and neuroimaging expertise, the company's Cortical Disarray Measurement (CDM®) technology uses MRI brain scan data to create products to support early and differential diagnosis, track progression, and predict the decline of neurodegenerative diseases. Oxford Brain Diagnostics is committed to assessing brain health based on changes in the cellular structure, supporting drug development, and helping clinicians around the world in their fight to defeat Alzheimer's and other neurodegenerative diseases.