NeuroSpectrum Insights, Inc
376 Main Street | Suite 105 | Bedminster | N.J. 07921

NeuroSpectrum Insights Receives Marketing Clearance for GyriCalc™ Software

Innovative Brain Mapping Technology Aims to Support Earlier Interventions for Neurological Conditions

Bedminster, NJ – July 28, 2025 – NeuroSpectrum Insights, Inc. (NSI), a pioneering medical device company specializing in advanced neuroimaging software, today announced clearance of its 510(k) application to the U.S. Food and Drug Administration (FDA) for its first product, GyriCalc™. The FDA notification, received on July 22, 2025, marks a major milestone in NSI's commitment to providing clinicians with cutting-edge tools for early and accurate brain measurements in young children.

GyriCalc™ is an innovative software solution designed to measure and analyze brain structures by processing structural magnetic resonance imaging (MRI) data for children between the ages of 24 and 36 months. It automatically labels, visualizes, and volumetrically quantifies segmentable brain structures, offering clinicians a more accurate 3D representation of the brain's physical formation. Key features of GyriCalc include the ability to measure the thickness of cerebral white matter gyrification, analyze brain shape, and produce detailed reports of its findings.

The development of GyriCalc™ is rooted in years of collaborative research conducted by leading experts in bioimaging, bioengineering, neurology, and psychiatry. Notably, studies have demonstrated that specific regions of the cerebral cortex and their surface characteristics, known as "gyri" and "sulci," are important neurodevelopmental markers.

"Our mission at NeuroSpectrum Insights is to harness transformational software technology to support early decision-making in clinical settings," said Andy Stewart, CEO of NeuroSpectrum Insights. "Marketing clearance of GyriCalc™ represents a pivotal step toward equipping healthcare professionals with an objective tool they can use to more precisely identify neurological conditions at an earlier stage."

In on-going conversations with NSI University of Louisville collaborators, there is significant appreciation that "therapy could be the difference between an individual needing full-time care and being independent, holding a job and living a fulfilled life," according to Ayman El-Baz, PhD, professor and chair of the J.B. Speed School of Engineering. Furthermore, bioimaging/bioengineering researchers at University of Louisville point out, "Autism research shows fewer than half of kids are tested before they turn 3. Therapy can be most effective in early childhood when brains are more elastic, but there are too many patients and too few specialists needed for diagnosis." Additionally, "Studies that we have done in children this age show that the outcomes are much better for children if they have that earlier intervention in terms of supports," offers Gregory Barnes, MD, PhD, professor of neurology and executive director of the Norton Children's Autism Center in Louisville, Kentucky. "As a result, there's an urgent need for new, objective technology that can help diagnose kids early". NSI intends to continue its collaboration with the University of Louisville and other investigators to advance its technology.

NeuroSpectrum Insights is dedicated to advancing neurological health through innovative technology. The company envisions a world where clinicians have the ability to uncover neurological conditions as early as possible, paving the way for timelier interventions and better patient outcomes.

For more information about NeuroSpectrum Insights, please visit https://neurospectruminsights.com.

Media Contact:

NeuroSpectrum Insights, Inc.
Email: mthomas@neurospectruminsights.com
Phone: (215) 801-1870

Note: This press release contains forward-looking statements, which are subject to risks and uncertainties. Actual results may differ materially from those projected.