Ceribell Receives FDA 510(k) Clearance for Use of Clarity® Algorithm for Neonates

November 24, 2025

Becomes the first and only FDA-cleared seizure detection algorithm for pre-term neonates through adults enabling rapid bedside detection, diagnosis, and treatment of non-convulsive seizures

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SUNNYVALE, Calif., Nov. 24, 2025 (GLOBE NEWSWIRE) -- CeriBell, Inc. (Nasdaq: CBLL) (“Ceribell”), a medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for its next-generation Clarity® algorithm to detect electrographic seizures in newborns pre-term and older. This clearance makes the Ceribell System the first and only AI-powered point-of-care electroencephalography (EEG) technology available to detect electrographic seizures in all ages of patients, from pre-term neonates through adults.

Early detection of seizures represents a critical unmet need in neonatal care. While approximately 9% of neonatal intensive care unit (NICU) patients may be diagnosed with seizures,[2,3] research suggests that up to 90% go undetected without EEG monitoring.[4] As a result, a significant portion of NICU patients could benefit from expanded EEG screening. Today, many NICUs lack the capability to provide timely EEG administration and continuous monitoring for their patients, resulting in unnecessary transfers, delayed treatment, and poor outcomes. High-risk newborns who spend more than 13 minutes seizing in an hour may have an 8-fold increased chance of poor outcomes, including mortality and long-term disability.[5] Underscoring the importance of timely intervention, recent guidelines from the American Clinical Neurophysiology Society recommend continuous EEG monitoring for neonates with a wide range of conditions that place them at high risk for seizures, including hypoxic-ischemic encephalopathy, congenital heart disease, and prematurity.[6]

Ceribell’s 510(k) clearance was supported by EEG data from more than 700 patients, representing the largest known validation dataset ever used for a neonatal seizure detection system. In addition, Ceribell previously received 510(k) clearance for a headcap specifically optimized for the neonatal population. By combining proprietary algorithms with purpose-built hardware, the Ceribell System enables clinicians to detect non-convulsive seizures in neonatal patients in real time, supporting rapid diagnosis and treatment to help prevent serious brain injury.

“Seizures are the most common neurological emergency in newborns, and protecting these fragile brains is essential to their long-term development and well-being,”[7] said Jane Chao, Ph.D., co-founder and CEO of Ceribell. “This FDA clearance enables us to further expand availability of Ceribell’s rapid, AI-powered neurological monitoring technology and serve more patients in need. Every newborn deserves timely and accessible seizure detection, without the delays and transfers that too often put outcomes at risk.”

“Ceribell’s easy-to-use, AI-powered point-of-care EEG helps address a critical gap in neonatal care by enabling prompt bedside neurological assessment and delivering real-time insights about each patient’s condition,” said Dr. Janene Fuerch, Medical Director of Neonatal ECMO at Stanford Children’s Hospital. “I have seen firsthand that many NICUs do not have 24/7 access to EEG. There is a clear need for faster, more accessible tools to evaluate brain activity at the bedside – especially in those critical first hours of life.”

References

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6. Wusthoff, C. et al. (2025). The American Clinical Neurophysiology Society Guideline on Indications for Continuous Electroencephalography Monitoring in Neonates. 2025 Jan 1;42(1):1-11
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Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other statements that are not statements of historical fact. Forward-looking statements can be identified by the use of words such as “will,” “may,” “could,” “likely,” “ongoing,” “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “assume,” “target,” “forecast,” “guidance,” “goal,” “objective,” “aim,” “seek,” “potential,” “hope,” and other words of similar meaning. These statements are based on management’s current expectations and assumptions and involve risks and uncertainties that could cause actual results to differ materially from those described. Such risks and uncertainties, including those related to regulatory approvals, clinical use and adoption, market acceptance, competition, and other factors, are described under the “Risk Factors” sections of our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and other reports filed with the U.S. Securities and Exchange Commission (“SEC”). These filings are available on the SEC’s website at https://sec.gov/ and on Ceribell’s website at https://investors.ceribell.com/. Ceribell undertakes no obligation to update any forward-looking statements as a result of new information, future events, or otherwise, except as required by law.

About CeriBell, Inc.
Ceribell is a medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions. Ceribell has developed the Ceribell System, a novel, point-of-care electroencephalography (“EEG”) platform specifically designed to address the unmet needs of patients in the acute care setting. By combining proprietary, highly portable, and rapidly deployable hardware with sophisticated artificial intelligence (“AI”)-powered algorithms, the Ceribell System enables rapid diagnosis and continuous monitoring of patients with neurological conditions. The Ceribell System is FDA-cleared for detecting suspected seizure activity and currently utilized in intensive care units and emergency rooms across the U.S. Ceribell is headquartered in Sunnyvale, California. For more information, please visit www.ceribell.com or follow the company on LinkedIn.

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