Ceribell Receives FDA 510(k) Clearance for First-of-its-Kind Delirium Monitoring Solution

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Novel technology paves the way for use of the company's industry-leading point-of-care electroencephalography (EEG) system to address long unmet need in delirium monitoring

SUNNYVALE, Calif., Dec. 09, 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 proprietary delirium monitoring solution,[1] the first and only FDA cleared delirium screening and monitoring device. This clearance further establishes the Ceribell System as an AI-powered brain monitoring platform technology, extending the benefits to a larger population of critically ill patients and providing additional information to assist in diagnosing patients at risk for both seizures and delirium.

"Delirium has severe consequences for critically ill patients, including increased mortality, prolonged hospital stays, and long-term cognitive impairment, resulting in substantial burdens for families and healthcare systems," said Juliana Barr, MD, professor emerita of anesthesiology, perioperative and pain medicine at Stanford University School of Medicine. "Current detection methods rely on intermittent, labor-intensive bedside assessments that are subject to human variability. Ceribell offers a reliable continuous monitoring solution that has the potential to improve delirium detection rates and management, and reduce the high costs associated with missed or delayed diagnoses."

Ceribell's delirium monitoring solution continuously analyzes EEG segments and notifies clinicians when patterns associated with delirium are detected, supporting more timely, reliable evaluation, and continuous monitoring of delirium. This will allow the Ceribell System to simultaneously support continuous seizure, electrographic status epilepticus (ESE), and delirium monitoring at the bedside.

Ceribell's delirium algorithm was validated using EEG data and clinical assessments collected through rigorous prospective studies involving 225 adults aged 22 years or older in critical care environments. This validation underscores the algorithm's reliability and real-world utility for continuous delirium monitoring in the critical care setting. FDA clearance follows Ceribell's initial receipt of a Breakthrough Device Designation for delirium monitoring in 2022. Ceribell has submitted a New Technology Add-on Payment (NTAP) application to the Centers for Medicare and Medicaid Services (CMS) for this new indication.

Delirium is a common and serious neurological condition affecting ~31% of ICU patients, and up to 80% of those who are mechanically ventilated.[2,3] It is associated with poor clinical outcomes, including a 10% higher 6-month mortality risk for every day delirium is experienced,[4] as well as longer hospital stays and increased hospitalization costs.[5] The risk of post-ICU dementia is 60% higher in discharged ICU patients who have had delirium, compared to those who have not had delirium in the ICU.[6] Current Society of Critical Care Medicine guidelines recommend regular delirium assessment using validated tools,[7] underscoring the need for early and accurate detection. Nonetheless, delirium - particularly hypoactive delirium[8] - often goes unrecognized due to challenges in clinical assessment and the lack of objective, continuous monitoring tools. Ceribell's delirium monitoring solution addresses this gap by providing real-time, objective neurological insights at the bedside.

Moreover, studies have demonstrated a relationship between seizure and delirium, with one study showing that ~48% of patients experiencing seizures in the ICU had peri-ictal delirium,[9] and another study finding epileptiform discharges in 42% of older ICU patients with delirium.[10] By combining advanced seizure and delirium monitoring capabilities, the Ceribell System will help clinicians better understand patient presentation and support more timely clinical decision making.

"Delirium has been under recognized and under treated in critically ill patients for far too long, despite its strong association with poor outcomes," said Jane Chao, Ph.D., co-founder and CEO of Ceribell. "With this FDA clearance, Ceribell is proud to expand EEG technology into delirium care, bringing the first objective, continuous monitoring solution to clinicians who urgently need better tools to support these vulnerable patients. We expect to finalize our go-to-market strategy in the near future, and look forward to leveraging our existing commercial footprint and reputation as the category leader in AI-based neuro monitoring to bring this transformational technology to patients in need. This is another big step towards our mission of making EEG a new vital sign for better brain care."

References

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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 seizure and delirium for use 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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