



Ceribell Receives FDA 510(k) Clearance for Quantitative EEG Trending and Amplitude-Integrated EEG Analysis

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New clearance to further simplify bedside EEG interpretation and enable more informed interventions for patients of all ages across multiple indications

SUNNYVALE, Calif., Sept. 30, 2026 (GLOBE NEWSWIRE) -- CeriBell, Inc. (Nasdaq: CBLL) ("Ceribell" or the "Company"), 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 cleared new software for the Ceribell System that makes it easier and faster for clinicians to interpret longitudinal brain activity and make appropriate clinical decisions.¹

Brain monitoring with electroencephalography (EEG) can generate hours of complex data that can be difficult to interpret in a timely manner. Ceribell's newly cleared software takes that raw information and turns it into simple, easy-to-read trends at the bedside, so clinicians can spot meaningful changes in brain activity sooner when every minute matters.

The software update will add three capabilities to the Ceribell Platform:

- **Alpha-Delta Ratio (ADR) & Relative Alpha (RA) Trending:** Delivers continuous brain monitoring which can be used to help catch early signs of brain distress and reduced blood flow in high-risk patients, such as those suffering from aneurysmal subarachnoid hemorrhage (SAH), enabling proactive intervention.
- **Burst Suppression (BS) Monitoring:** Provides a clear, real-time picture of brain activity that can be used to help clinicians safely fine-tune sedation drugs when treating severe, ongoing seizures or controlling brain swelling.
- **Amplitude-Integrated EEG (aEEG):** Offers simplified, long-term monitoring of background brain activity, bringing standard-of-care neonatal assessment to the NICU while complementing adult ICU monitoring.

Notably, this clearance carries no age restriction. The same easy-to-use trends are available whether the patient is a premature newborn in the NICU or an adult patient in the emergency department or ICU.

"In critical care, time is brain, and every hour spent waiting for interpretation of EEG is time lost delivering treatment at the bedside," said Jane Chao, Ph.D., co-founder and CEO of Ceribell. "We expect to integrate these new features through an automatic software update in the first half of 2027."

The introduction of these algorithms will build on Ceribell's continued expansion of its AI-powered EEG platform across the acute-care setting, including recent clearances for neonatal seizure detection² and delirium monitoring.³ Together, these updates reflect Ceribell's ongoing commitment to making comprehensive brain monitoring available to a wider variety of patients — regardless of age or care setting.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact, including statements regarding the benefits of Ceribell's technology and the continued evolution of the Ceribell platform, are forward-looking statements. 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, including those related to regulatory approvals, clinical use and adoption, market acceptance, and competition, as described under the "Risk Factors" sections of the Company's 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 and on Ceribell's investor relations website. 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. Ceribell is headquartered in Sunnyvale, California. For more information, please visit www.ceribell.com or follow the company on LinkedIn.

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¹ [FDA 510\(k\) Clearance Letter K261712](#)

² [FDA 510\(k\) Clearance Letter K252070](#)

³ [FDA 510\(k\) Clearance Letter K251936](#)