Ceribell Receives FDA Breakthrough Device Designation for LVO Stroke Detection and Monitoring Solution

January 5, 2026

Clearance would position the Ceribell System as the first and only point-of-care electroencephalography (EEG) technology to aid in detection and monitoring of Large Vessel Occlusion (LVO) stroke in the hospital setting

SUNNYVALE, Calif., Jan. 05, 2026 (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 Breakthrough Device Designation for its Large Vessel Occlusion (LVO) stroke detection monitor for patients in the hospital setting. This first-in-class LVO stroke detection monitor uses Ceribell's existing hardware and applies an AI-based algorithm to interpret EEG signals for early detection of LVO stroke.

The Breakthrough Device Designation for LVO Stroke represents the latest achievement in Ceribell's continued efforts to extend its point-of-care EEG brain monitoring technology to additional indications, building on recent FDA 510(k) clearances for its next-generation Clarity® algorithm to detect electrographic seizures in neonates (November 2025) and its proprietary delirium screening and monitoring solution (December 2025).

Nearly 800,000 strokes occur annually in the U.S.[1] In particular, LVO strokes are medical emergencies and have disproportionately higher morbidity and mortality compared to non-LVO ischemic stroke, contributing to ~62% of post-stroke dependence and ~96% of post-stroke mortalities.[2] Timely detection and access to treatment of LVO stroke can result in tremendous health benefits over patients' lifetimes, with every minute saved associated with a week of disability-free life. [3]

Unlike community-onset stroke, which occurs outside the hospital and often triggers immediate emergency response, in-hospital stroke affects patients who are already admitted. Scientific literature shows that stroke detection and treatment in hospitalized patients are often significantly delayed compared to strokes occurring outside of hospitals.[4,5,6] This leads to worse outcomes, as patients face about three times higher rates of mortality, and are half as likely to be discharged home compared to community-onset stroke, even after adjusting for clinical characteristics and comorbidities in hospitalized patients.[7] Out of 800,000 stroke patients, up to 17% are in-hospital-onset stroke.[4,5]

Dr. Chitra Venkatasubramanian, MBBS, MD, MSc, FNCS, Clinical Professor of Neurology and Neurosurgery, notes that: "In-hospital strokes frequently occur in units that aren't specialized in neurology, where bedside teams may not have sufficient training or tools to detect subtle neurological changes concerning a stroke. Many of these patients are recovering from surgery, intubated, ventilated, or on medications that complicate their assessment, making it incredibly difficult to spot the early signs of a stroke. A tool that continuously monitors brain function and alerts the care team the moment something is wrong would allow us to intervene sooner and facilitate achieving better outcomes for patients."

The Breakthrough Device Designation recognizes the potential of Ceribell's LVO stroke detection monitor to enable timely and accurate LVO detection compared to the current standard-of-care, supported by validation through rigorous, prospective, multi-center studies using EEG data and clinical assessments. "Stroke is a devastating condition, but one where quick access to treatment can make a lifetime of a difference," said Jane Chao, Ph.D., co-founder and CEO of Ceribell. "At a time when minutes matter, patients with in-hospital stroke often experience hours of delay. Ceribell is proud that this FDA Breakthrough Device Designation recognizes the potential of the Ceribell System to provide accurate and timely detection of LVO stroke for this vulnerable patient population."

The LVO Breakthrough Device designation is another critical milestone that further reinforces Ceribell's mission to make EEG a new vital sign for better brain care.

References

[1] Martin, S. S., et al. (2025). 2025 Heart disease and stroke statistics: A report of US and global data from the American Heart Association. Circulation, 151(8), e41–e660. https://doi.org/10.1161/CIR.0000000000001303

[2] Malhotra, et al. (2017). Ischemic strokes due to large-vessel occlusions contribute disproportionately to stroke-related dependence and death: A review. Frontiers in Neurology, 8, 651.https://doi.org/10.3389/fneur.2017.00651

[3] Meretoja, A. et al. (2017). Endovascular therapy for ischemic stroke: Save a minute — save a week. Neurology, 88(22), 2123–2127. https://doi.org/10.1212/WNL.0000000000003981

[4] Nouh, A. et al. (2022). Identifying best practices to improve evaluation and management of inhospital stroke: A scientific statement from the American Heart Association. Stroke, 53(4), 165–175. https://doi.org/10.1161/STR.0000000000000402

[5] Cumbler, E. (2015). In-hospital ischemic stroke. The Neurohospitalist, 5(4), 173–181. https://doi.org/10.1177/1941874415588319

[6] Cummings, S. et al. (2022). Delays in the identification and assessment of in-hospital stroke patients. Journal of Stroke and Cerebrovascular Diseases, 31(4), 106327. https://doi.org/10.1016/j.jstrokecerebrovasdis.2022.106327

[7] Cumbler, E. et al. (2014). Quality of care and outcomes for inhospital ischemic stroke: Findings from the National Get With The Guidelines-Stroke. Stroke, 45(1), 231–238. https://doi.org/10.1161/STROKEAHA.113.003617

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 use in detecting seizure and delirium 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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