Minder® System Cleared for Patients 12 -75 Years of Age

Highlights:

- The U.S. Food and Drug Administration (FDA) has cleared the Minder® System to include patients aged 12 years and older with drug-resistant epilepsy, broadening eligible access beyond the original clearance for patients 18 years of age and older.
- The FDA clearance was supported by clinical and technical data demonstrating the safety and performance of the Minder System in adolescent patients, including biocompatibility and device performance data specific to adolescent anatomy and physiology.
- This age expansion opens access to the world's first implantable sub-scalp continuous EEG monitoring device for a significant adolescent patient population, for whom drug-resistant epilepsy carries profound consequences for development, education, and quality of life.

Melbourne, Australia & Dallas, United States – 30 October 2026 – Epiminder Limited (ASX: EPI), developer of the world's first FDA-authorized long-term implantable continuous EEG monitoring (iCEM®) system, today announced that the FDA has cleared an expansion for the age range of the Minder® System to include patients aged 12 years and older with drug-resistant epilepsy (DRE). The Minder System was originally cleared for adults 18 years of age and older. The clearance broadens the eligible patient population for the technology, enabling US clinicians to offer continuous EEG monitoring to adolescent patients for the first time.

Epilepsy affects an estimated 3.4 million Americans and is categorized as drug resistant in approximately one-third of the cases. An important population are children and adolescents for whom seizure burden remains high despite two or more antiseizure medications. Adolescence is a particularly high-stakes period for individuals with DRE: uncontrolled seizures during these years carry significant consequences for cognitive development, educational achievement, and independence. Despite this, continuous EEG monitoring for adolescent patients has historically required hospitalization in an epilepsy monitoring unit (EMU), limiting access to short, episodic windows that frequently fail to capture the seizure activity clinicians need to see.

The Minder System addresses this access gap by providing continuous, ambulatory sub-scalp EEG data transmitted wirelessly to a secure cloud platform and reviewed remotely by the patient's care team. The system consists of an implantable sub-scalp electrode array, an implantable telemetry unit placed behind the ear, and a wearable that charges the device and transmits data. The sub-scalp placement is minimally invasive relative to intracranial devices and does not penetrate the skull. The clearance was supported by a comprehensive submission encompassing device performance, biocompatibility, and clinical safety data specific to the adolescent anatomy and physiology.

Dr Rohan Hoare, CEO of Epiminder, said, “This clearance is a meaningful step forward for patients and for the epilepsy community. Adolescence is a particularly vulnerable period for individuals living with drug-resistant epilepsy – uncontrolled seizures during these years carry profound consequences for development, education, and independence. With this clearance, US neurologists can now offer the Minder System to their teenage patients, giving them access to continuous, objective EEG data over the timescales needed to guide real treatment decisions. We have always believed that every patient who could benefit from continuous EEG monitoring deserves access to it, and this clearance brings us meaningfully closer to that goal.”

Dr R. Edward Hogan, Past President of the American Epilepsy Society said, “For adolescents with drug-resistant epilepsy, many of our most important treatment decisions still rest on seizure diaries and brief hospital admissions that may not capture appropriate events. The Minder System opens a door to objective, continuous capture of seizure activity in these patients while they are at home, at school, and going about their daily lives. That creates new possibilities for how we care for them. We can see how often seizures are truly occurring, identify events that would otherwise go unrecognized, and base medication and treatment decisions on objective data rather than recall alone. For young people whose development, education, and independence are all at stake, that clarity matters enormously.”

Dr Tracy Cameron, Vice President of Clinical and Regulatory Affairs at Epiminder, said, “Achieving 510k clearance to extend the Minder System indication to patients 12 and older reflects the rigor of our regulatory program and the quality of our clinical and engineering teams. This clearance also strengthens our regulatory foundation as we continue to evaluate additional indications and platform enhancements for the Minder System.”

This announcement has been approved by the Board of Directors of Epiminder Limited.

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About Minder®

Minder® is a minimally invasive implantable continuous EEG Monitoring (iCEM®) device that provides clinicians and patients with long-term, objective data on brain electrical activity. The system continuously records bilateral subscalp EEG and transmits data via an external wearable and smartphone application to a secure cloud

platform. Patients wear the device during their normal daily activities, enabling real-world monitoring over months or years.

The Minder® System was authorised by the FDA via the de novo pathway and is being used in DETECT as a marketed device in a post-market study. The UMPIRE first-in-human multicentre trial, published in Epilepsia (2025), demonstrated Minder's safety and high-quality signal acquisition across extended monitoring periods.

About Epiminder

Founded in 2017 by Professor Mark Cook together with the Bionics Institute, St Vincent's Hospital, the University of Melbourne and Cochlear Limited, Epiminder is a medical device and information solutions company focused on developing diagnostic and treatment tools for epilepsy and other seizure disorders where continuous monitoring is required. Epiminder is headquartered in Melbourne, Australia and has offices in the United States.