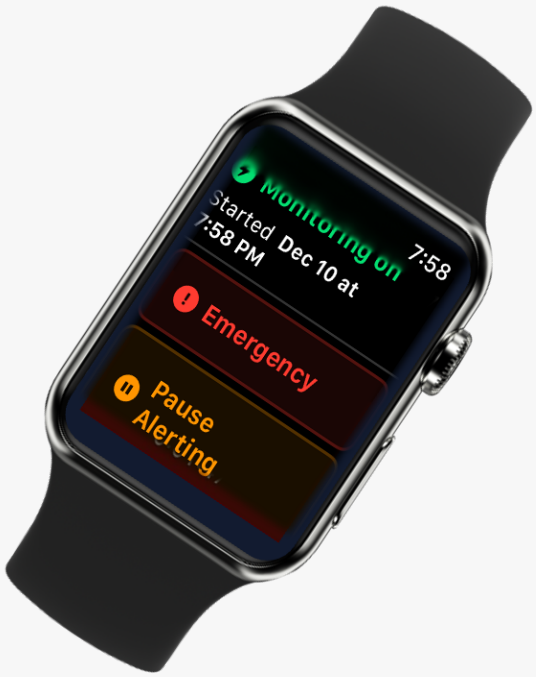
EpiWatch, Inc. Announces FDA 510(k) Clearance for the EpiWatch Continuous Seizure Monitor

Innovative EpiWatch Continuous Seizure Monitor uses widely worn Apple Watch to detect and alert for seizures for individuals living with epilepsy



EpiWatch seizure detection runs on Apple Watch

BALTIMORE, MD, UNITED STATES, March 19, 2025 /EINPresswire.com/ -- EpiWatch, Inc., a commercial stage company spun-out from Johns Hopkins University, today announced that it has received FDA 510(k) clearance to market EpiWatch in the United States. EpiWatch® is a Continuous Seizure Monitor (CSM™) platform that works with Apple Watch to help detect and alert for tonic-clonic seizures in people with epilepsy.

“This marks a significant step forward in fulfilling our mission to empower all people living with epilepsy and deliver innovation that keeps people with epilepsy safe, and enables them, their caregivers and their clinicians to better manage their condition while providing peace of mind for their caregivers and loved ones,” stated Teresa Prego, EpiWatch CEO. “EpiWatch will now partner with clinicians and early users for a limited market release aimed at optimizing product use and identifying and understanding key educational and support needs for EpiWatch users.”

The integration of this proprietary algorithm for tonic-clonic seizure detection and alerting with a widely worn wearable device, Apple Watch, offers significant benefits, including enhanced safety and security of individuals living with epilepsy while also providing discreet monitoring—something that is important for those seeking to avoid the stigma often associated with traditional condition-specific wearable devices. Studies have shown that seizure detection and timely alerts can improve seizure management, safety, and emergency response for individuals, their families, and urgent response teams. Additionally, notification of seizure activity

can help prevent Sudden Unexpected Death in Epilepsy (SUDEP), a leading cause of premature death in patients with epilepsy.

This FDA clearance follows the successful conclusion of the clinical trial, EpiWatch: Evaluation of a Non-EEG Physiologic Signal-Based Seizure Monitoring System, a multi-center study conducted at leading epilepsy centers. The results of the trial demonstrated that EpiWatch offers a high seizure detection rate with a low false alarm rate, making it a valuable tool in the ongoing management of seizures and epilepsy.

As the first and only FDA-cleared seizure detection app on Apple Watch, EpiWatch is the product of a long-term collaboration between EpiWatch and Johns Hopkins Medicine. Initially developed using Apple's ResearchKit platform, EpiWatch represents a major advancement in epilepsy monitoring technologies, within the consumer-friendly Apple Watch ecosystem.

About EpiWatch, Inc.
EpiWatch, Inc., a commercial-stage company spun out from Johns Hopkins University is leading the digital transformation of epilepsy care. With the first and only FDA cleared seizure detection and alerting app for Apple Watch, EpiWatch delivers an innovative and integrated solution that keep people with epilepsy safe, and empowers patients, their caregivers, and physicians to better manage their condition. Founded by world-renowned epileptologists Greg Krauss and Nathan Crone, EpiWatch is addressing the needs of the 3.4 million Americans living with epilepsy, 40% of whom experience seizures that are uncontrolled or poorly controlled by current medical therapies. Beyond the profound impact of seizures on quality of life—including social isolation, loss of independence, family stress, and underemployment—uncontrolled seizures can lead to injuries or even death due to Sudden Death in Epilepsy (SUDEP). By providing early detection and alerting, EpiWatch's technology aids in the care and management of individuals living with epilepsy, offering crucial peace of mind to patients, their families, clinicians and caregivers. For additional information, visit www.epiwatch.com

About the Clinical Study
EpiWatch: Evaluation of a Non-EEG Physiologic Signal-Based Seizure Monitoring System, was a multi-year, multi-site Phase III clinical study conducted at leading epilepsy centers including Johns Hopkins Hospital, LeBonheur Children's, Children's National Medical Center, Thomas Jefferson University, and Johns Hopkins All-Children's Hospital. Study participants included individuals diagnosed with epilepsy or suspected epilepsy ages 5 and up.

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