

First U.S. patient initiated in pivotal multi-center study for U.S. approval of the UNEEG EpiSight™ solution: a disruptive technology that may advance biomarker-based therapy for people with epilepsy

- UNEEG EpiSight™ solution based on the 24/7 EEG™ SubQ implant aims to offer healthcare providers and patients with epilepsy continuous and accurate EEG biomarker information to support disease management goals.
- Pivotal multi-center study for U.S. approval conducted with the highly accredited epilepsy programs at the University of Pennsylvania and Mayo Clinic in the U.S. and Freiburg University Hospital in Germany.
- Potential to disrupt the treatment regime for patients with severe uncontrolled epilepsy by putting biomarker-based insight in the hands of the patient, the family, and the health care team.
- Epilepsy Foundation Shark Tank Competition winner.

COPENHAGEN, DK and LISLE, IL, U.S. – June 15th 2021 - UNEEG medical, a company pioneering technologies that collect, monitor, and analyze brain activity, to improve diagnostics and treatment within epilepsy, announce initiation of the first U.S. patient in the U.S. pivotal clinical evaluation of the company's flagship program for ultra long-term electroencephalogram (EEG) recording. The UNEEG EpiSight™ solution has been available in the European Union since 2019, and the pivotal U.S. study will further expand the in-use validation ongoing at major epilepsy hospitals in Europe.

The study is a 12-week open-label, prospective trial with a paired, comparative design for pivotal evaluation of the safety and effectiveness of the UNEEG EpiSight™ solution in patients with temporal lobe epilepsy. The UNEEG EpiSight™ solution with the 24/7 EEG™ SubQ implant will be compared to simultaneously recorded video-EEG in the Epilepsy Monitoring Unit and to self-reported seizure logbooks. (www.clinicaltrials.gov, NCT04526418)

“It's very important that we find new ways to monitor seizure activity in a consistent and objective manner over long periods of time to help people with epilepsy that do not respond adequately to medication and continue to suffer from unpredictable and sometimes life-threatening seizures,” says lead investigator **Jay Pathmanathan, MD, PhD, an assistant professor of Clinical Neurology and Director of Electroencephalography (EEG) at the Perelman School of Medicine at the University of Pennsylvania**. He continues: “Our hope is that such ultra long-term monitoring can provide an important late-stage diagnostic indicator to optimize therapy significantly better for patients with often very individual needs.”

The Epilepsy Foundation, a U.S. patient advocacy organization leading the fight to overcome the challenges of living with epilepsy, recognized the UNEEG EpiSight™ solution in 2017 as a promising technology. “We are very proud that Epilepsy Foundation Shark Tank Competition winner UNEEG medical has reached this stage of clinical testing for its novel approach,” says **Jacqueline A. French, M.D., Professor, Department of Neurology at NYU Grossman School of Medicine and Chief Medical and Innovation Officer for the Epilepsy Foundation**. She continues: “The Shark Tank Competition is about technologies that improve the treatment and care of epilepsy patients and hold promise for the individual patient, the treating health care team, and researchers seeking to ultimately cure epilepsy.”

UNEEG medical's CEO, Torben Sandgren, concludes: "We believe that the UNEEG EpiSight™ solution may represent one of the most innovative solutions for people with treatment resistant epilepsy. There is no other device like this approved in the U.S. and as such we are pioneering the field of convenient and minimally invasive ultra long-term monitoring solutions." He states: "We see many opportunities that our technology may disrupt the treatment regime for patients with severe uncontrolled epilepsy by putting biomarker-based insight in the hands of the patient, the family, and the health care team."

About UNEEG EpiSight™ solution based on the 24/7 EEG™ SubQ implant

The UNEEG EpiSight™ solution aims to provide physicians and patients a continuous and accurate recording of seizure activity for patients in their everyday life. The system is based on the 24/7 EEG™ SubQ minimally invasive implantable EEG recorder which together with UNEEG's proprietary software and data management systems constitute a simple solution for healthcare providers and patients.

Please be advised that the UNEEG EpiSight™ solution has not been approved by the FDA. UNEEG medical is commencing a U.S. clinical trial and intends to seek approval in the U.S.

About UNEEG medical

UNEEG medical is pioneering technologies that collect, monitor, and analyze brain activity, to improve diagnostics and treatment within epilepsy.

The company markets UNEEG EpiSight™, a solution utilizing the 24/7 EEG™ SubQ implant and proprietary software to provide continuous and accurate recording of seizure activity. Available in European markets since 2019, the company is preparing expansion of UNEEG EpiSight™ to markets in North America and Asia-Pacific. UNEEG EpiSight™ won the U.S. Epilepsy Foundation Shark Tank Competition in 2017.

Founded in 2005, UNEEG medical is headquartered in Copenhagen, Denmark, with presence in Illinois, U.S., and the United Kingdom. The company is owned by the Danish family-owned T&W Medical A/S having global activities within hearing aids and life-science activities employing more than 11,000 worldwide thereof 2,400 in the U.S.

For more information, visit UNEEG.com.

About Epilepsy Foundation

With a network of partners throughout the U.S., the Epilepsy Foundation is leading the fight to overcome the challenges of living with epilepsy. The Foundation connects people to treatment, support, and resources; leads advocacy efforts; funds innovative research and the training of specialists; and educates the public about epilepsy and seizure first aid. To learn more visit epilepsy.com

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