



Press Release

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## **Optima Neuroscience's IdentEvent™ EEG Review Software Receives FDA Clearance**

*Alachua, FL* - Optima Neuroscience received clearance from the U.S. Food and Drug Administration (FDA) to market the company's first clinical product, IdentEvent™. IdentEvent incorporates the company's innovative seizure detection technology designed to aid doctors in reviewing complex recordings of the brain's electrical activity (EEGs).

Based on extensive research that began at the University of Florida, IdentEvent was designed to assist sub-specialty neurologists in the difficult and tedious task of reviewing long-term EEG recordings. The software utilizes a proprietary algorithm to accurately identify areas of interest for the physician, allowing them to quickly navigate through a recording to determine if seizure activity has occurred. In addition to improved performance, IdentEvent offers a unique, intuitive user-interface that requires little to no user training.

President Dr. Ryan Kern commented on the FDA clearance stating, "This is truly an exciting day for Optima. Since the company's inception in 2005, our team has been working diligently towards bringing our technology to market. FDA clearance will allow Optima to begin IdentEvent sales and start to see our hard work directly benefit patient care."

Optima's IdentEvent 510(k) submission was supported by the pivotal clinical trial of its groundbreaking seizure detection technology. Funded by the National Institutes of Neurological Disease and Stroke (NIH/NINDS) Grant 5-R01-NS050582, Optima partnered with the Allegheny-Singer Research Institute (Pittsburgh, PA) and the Medical University of South Carolina (Charleston, SC) to validate how accurately the company's algorithm detects seizure activity. In a side by side comparison with the current market-leading product, Optima's clinical performance drastically surpassed the competition by generating 85% less false detections (2 per day v. 13+ per day), while offering comparable sensitivity.

"IdentEvent's ability to accurately identify seizures will make it the most clinically-useful EEG review software on the market." reports Dr. J. Chris Sackellares, Chief Scientific Officer. "Our technology's drastic reduction in false detections will allow the neurologist to focus only on the areas of a recording that are of clinical interest. Given the limited number of subspecialists trained to interpret EEGs, IdentEvent will allow for more efficient and cost-effective diagnosis and management of patients suffering from seizure disorders."

## **About Optima**

*Optima Neuroscience is a medical device company producing a line of revolutionary brain monitoring products. Based in Alachua, FL, the company is commercializing technology originally invented by researchers at the renowned University of Florida McKnight Brain Institute. As pulse oximeters revolutionized the monitoring of lung function, Optima's products will enable non-specialist care providers to rapidly and accurately obtain critical information about the status of the brain. Visit our website at [www.optimaneuro.com](http://www.optimaneuro.com).*

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