



Cala Health Receives FDA Clearance for Cala ONE and Presents New Evidence at American Academy of Neurology Annual Meeting

A new class of non-invasive, electrical medicine begins as FDA grants a De Novo request for the first-ever body-worn stimulator to treat a movement disorder.

Burlingame, CA – April 26, 2018 – Cala Health announced today that the US Food and Drug Administration (FDA) has granted a De Novo request for Cala ONE, an individualized prescription neuromodulation therapy for transient relief of hand tremors in adults with essential tremor (ET). Cala ONE is the first-ever non-invasive, targeted nerve stimulator for the treatment of ET to receive FDA marketing authorization. Evidence on Cala ONE was presented as part of a late-breaking emerging science session at the American Academy of Neurology 70th Annual Meeting in Los Angeles, CA on April 25, 2018 by Rajesh Pahwa, MD, University of Kansas Medical Center.

Essential tremor affects over 7 million Americans and millions more worldwide, making it one of the most common movement disorders and 8 times more common than Parkinson's disease. The condition is marked by hand tremors that make it difficult to perform daily activities like eating, drinking and writing. Existing drugs are often ineffective and can have serious side effects. Though effective, deep brain stimulation, is costly, invasive and many patients are not candidates for the surgery. Cala ONE is worn on the wrist like a smart watch to deliver patterned electrical stimulation to nerves through the skin.

“Cala Health has brought together a team with expertise in neuroscience, medical devices, and digital therapeutics to develop a new class of therapies that give essential tremor patients relief from their hand tremors without invasive brain surgery or drugs,” shared Kate Rosenbluth, Founding CEO of Cala Health. “Receiving FDA authorization is an exciting milestone for our team and the patients we serve. It’s just the beginning for a new class of accessible electrical medicines.”

The evidence considered by the FDA included results from a randomized, controlled, multi-center study conducted at sites across the US. “The study showed that Cala ONE produced significant improvements in the treatment group in both physician and patient-rated measures of tremor severity compared to the sham group,” said Dr. Jill Ostrem, medical director of the Movement Disorder and Neuromodulation Center at University of California, San Francisco and an investigator in the study. “Reduction in tremor severity can allow patients to perform daily activities and improve their quality of life.”

The Cala ONE device delivers individualized therapy that is calibrated by a physician using on-board sensors to measure the individual's tremor. The compact therapeutic device can be worn all day to provide on-demand relief at home, in social settings, at work, or whenever patients desire relief.

About Cala Health, Inc.

Cala Health is a medical technology company pioneering a new class of electrical medicine. The company is merging innovations in neuroscience and electronics to deliver individualized, prescription neuromodulation therapies. These therapies treat chronic disease non-invasively by stimulating peripheral nerves with body-worn electronics. The company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology, including Johnson & Johnson Innovation – JJDC, Inc., Lux Capital, Lightstone Ventures, GV, dRx Capital and Action Potential Venture Capital.

For more information, please visit www.calahealth.com

