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FDA clears Nexstim's Navigated Brain Stimulation for non-invasive cortical mapping prior to neurosurgery

Allows marketing and sale of navigated TMS in the USA for the first time

HELSINKI--([BUSINESS WIRE](#))--Nexstim Oy, a medical device company, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Navigated Brain Stimulation System for use in the assessment of the primary motor cortex for pre-procedural planning.

Using transcranial magnetic stimulation (TMS) guided by standard MR-image data, Nexstim has developed Navigated Brain Stimulation (NBS), the first non-invasive direct technique for functional mapping of the motor cortex. In its FDA submission, Nexstim included data comparing the accuracy of NBS pre-operative mapping with the results of "gold standard" direct cortical stimulation during actual brain tumor surgery.

Neurosurgeons have long awaited a reliable, non-invasive, tool for pre-operative planning as an alternative to direct cortical stimulation, an invasive technique which is performed after craniotomy at the beginning of surgery. Cortical mapping with NBS is a major advance that may help in tailoring neurosurgical treatment and planning to the needs of the individual patient - potentially saving valuable time in the OR and helping ensure the best possible outcome for the patient.

Lothar Koob, Chairman of the Board of Nexstim commented, "This first FDA clearance for Nexstim marks an important milestone in the development of the company, and based on very encouraging feedback from clinicians we see many additional potential applications for our proprietary navigated brain stimulation technologies."

About Nexstim and Navigated Brain Stimulation

Nexstim was founded in 2000 to develop non-invasive Navigated Brain Stimulation (NBS) for diagnostic and therapy applications. With NBS an operator moves a hand-held TMS coil over the patient's head delivering a series of harmless magnetic pulses whose electric fields gently activate neurons in the cortex. Converting a standard head MRI into a 3D-model of the patient's brain, allows the operator to precisely navigate the coil's electric field anywhere in the cortex, much like driving a car with the aid of GPS. Measuring patient responses by electromyography (EMG) reveals the locations of the vital motor areas inside the brain.

With over 50 systems delivered to hospitals world-wide, NBS has multiple investigational neurodiagnostic applications, including stroke, as well as promising future applications in neurotherapy. Since 2007, Nexstim has raised EUR 14 million in new financing, led by European venture capital investors HealthCap and LSP, as well as Sitra. See www.nexstim.com.