NeuroMetrix Announces Sleep Indication for SENSUS Pain Management System

Business Wire

Key Step Towards Positioning SENSUS for Sleep Market

NeuroMetrix, Inc. [1], a medical device company focused on the treatment of the neurological complications of diabetes, reported that the SENSUS Pain Management System became the first transcutaneous electrical nerve stimulator to receive 510(k) clearance (K130919) from the U.S. Food and Drug Administration (FDA) for use during sleep.

SENSUS is a convenient and wearable non-invasive device that offers physicians and their patients a non-narcotic pain relief option as a complement to medications. The device is lightweight and can be worn during the day while remaining active. It is the only transcutaneous electrical nerve stimulator designed specifically for people with diabetes and chronic pain. The most common cause of such pain in people with diabetes is painful diabetic neuropathy (PDN), which affects up to 5 million people in the US alone. About half of patients with PDN suffer from sleep disturbances, which can aggravate their diabetes. With this expanded regulatory indication, the device may now be marketed for overnight use.

Under its draft guidance on transcutaneous electrical nerve stimulators for pain relief, the FDA requires that these devices carry a warning against use during sleep, primarily because of electrical hazards following dislodgement of electrodes. SENSUS utilizes a proprietary electrode peeling detection algorithm to address this risk.

“SENSUS is the first and only transcutaneous electrical nerve stimulator that specifically includes use during sleep within its 510(k) indications,” said Shai N. Gozani, M.D., Ph.D., President and Chief Executive Officer of NeuroMetrix. “We believe that growing recognition of the inter-relationship between chronic pain, such as painful diabetic neuropathy, and sleep disturbances is clinically important and represents a unique market position for SENSUS. We will build on this expanded indication by launching a series of novel sleep enabling features for SENSUS over the next 12 months.”

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