For Immediate Release
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Neuros Medical Receives FDA Approval for the Altius® Direct Electrical Nerve Stimulation System

The Altius® System represents a significant advancement in the treatment of chronic intractable post-amputation pain

ALISO VIEJO, California, August 28, 2024/PRNewswire/ -- Neuros Medical, Inc. announced today that it has received approval from the United States Food and Drug Administration (FDA) for its Altius® Direct Electrical Nerve Stimulation System.

The Altius® Direct Electrical Nerve Stimulation System is indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees.

The labeling for the Altius® System was based on the results of the QUEST study in which all primary efficacy and safety endpoints were met, demonstrating superiority of treatment over active-sham control. Patients receiving Altius® treatment reported statistically significant and lasting reductions in pain, decreased opioid use, and improvements in quality of life[1].

“Approval of the Altius® System represents a significant advancement for lower limb amputees who for years have suffered from chronic debilitating pain with largely ineffective treatment options,” said Dr. Leonardo Kapural MD, PhD, Professor of Anesthesiology at Florida Atlantic University and Partner at Carolinas Pain Institute and the QUEST Study National Principal Investigator. “We finally have a solution proven to reduce pain and improve quality of life and one backed by the first rigorous, randomized controlled trial conducted in this patient population.”

“The approval of the Altius® System by the FDA is a significant milestone in the treatment of post-amputation pain,” said David Veino, President & CEO, Neuros Medical.

“Physicians and patients now have a clinically proven treatment that addresses the underlying cause of post-amputation pain using an innovative on demand, patient-controlled device without the risk of addiction associated with opioids. We are grateful to the QUEST study investigators and study subjects who persevered through many challenges, including COVID, to bring the Altius® System to the amputee community.”

Neuros plans to begin commercialization of the Altius® System later this year. Please visit www.neurosmedical.com for more information.

Click here for important safety information.

About the Altius® Direct Electrical Nerve Stimulation System

The Altius® System is a patient-controlled, on demand system that uses Neuros’ patented technology to address the underlying cause of post-amputation pain by inhibiting pain signal transmission from the damaged peripheral nerves near the site of amputation to the central nervous system. The system consists of a nerve cuff electrode placed around an affected nerve and an implantable pulse generator (IPG). Patients initiate an on-demand 30-minute treatment session as needed for targeted pain relief.

The Altius® System received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) in 2021 and is the first device with this designation to receive FDA Approval in 2024. (The FDA Breakthrough Device Program is intended to help patients and health care providers receive timely access to medical devices that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions.)

About Neuros Medical, Inc.

There are nearly two million amputees in the U.S., with 185,000 new amputations occurring every year.[2,3] Post-amputation pain includes both phantom limb pain and residual limb pain, and impacts nearly one million Americans, representing a significant unmet medical need, as existing treatment options are limited and consist primarily of opioids and gabapentinoids. Neuros Medical is a privately held company and the maker of the Altius® Direct Electrical Nerve Stimulation System designed for the treatment of chronic post-amputation pain. Our mission is to reduce pain and restore life for people suffering with post-amputation pain. We are a passionate team guided by our core values and committed to our patients and the healthcare professionals who care for them.

Our Core Values: Patients First, Deliver Excellence, Responsible Ambition, Inspire and Empower.

References

[1]Kapural L, Melton J, Kim B, et al., Primary 3-Month Outcomes of a Double-Blind Randomized Prospective Study (The QUEST Study) Assessing Effectiveness and Safety of Novel High-Frequency Electric Nerve Block System for Treatment of Post-Amputation Pain. J Pain Res. 2024 Jun 6;17:2001-2014.

[2] Ziegler-Graham K, MacKenzie EJ, Ephraim PL, et al. Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil. 2008;89:422–42.

[3] Owings MF, Kozak LJ. Ambulatory and inpatient procedures in the United States, 1996. National Center for Health Statistics. Vital Health Stat 13(139). 1998.

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