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BIONESS ANNOUNCES FDA 510K CLEARANCE OF STIMROUTER® SYSTEM; A NOVEL, IMPLANTABLE NEUROMODULATION DEVICE DESIGNED TO TREAT CHRONIC PERIPHERAL PAIN

VALENCIA, CALIF. – February 23, 2015 – Bioness, Inc. announced that the U.S. Food and Drug Administration has cleared the StimRouter®, an implantable neuromodulation device designed to treat chronic, intractable pain of peripheral nerve origin. The StimRouter is the only implanted device to be cleared by the FDA with a specific indication for peripheral nerve stimulation.

With an estimated 50 million people suffering from chronic pain and burdening the U.S. healthcare system with $150 billion in annual costs, there's never been a greater need for innovative pain management options. As a minimally invasive implantable device designed to reduce pain by specifically targeting the affected peripheral nerve, the StimRouter is designed to be a cost-effective alternative to injections, ongoing medication regiments, and complex surgeries.

According to Bioness founder Alfred Mann, "the StimRouter is a disruptive technology that presents an opportunity to change the way healthcare professionals treat chronic peripheral pain by targeting and neuromodulating the affected nerve. Furthermore, the StimRouter represents a less invasive and more cost effective treatment method when compared to commercially available pain management implanted devices."

Bioness President and CEO Todd Cushman commented that, "the FDA clearance of StimRouter represents a monumental development for Bioness. The StimRouter builds on the success of our external neuromodulation systems and allows us to expand into the pain management market as well as other future applications. The positive clinical results, ease of use and a specific indication for use that targets peripheral nerve pain makes the StimRouter a unique and compelling alternative to Spinal Cord Stimulation (SCS) and opiates."

About StimRouter®
StimRouter is approved by the FDA to treat chronic pain of peripheral nerve origin. StimRouter is a minimally invasive neuromodulation medical device consisting of an implanted lead, external pulse transmitter (EPT) and conductive electrode, controlled by a small hand-held wireless control unit. Electrical signals are transmitted transdermally from the EPT through the electrode, down the lead to the origin of pain. Each system is programmed at the direction of the physician to meet the requirements of the patient.

StimRouter™
Neuromodulation System

About Bioness Inc.
Bioness is the leading provider of innovative technologies to help people regain mobility and independence and improve quality of life. The company provides neurological solutions for people suffering from hand and lower extremity paralysis, including the L300® Foot Drop System, L300® Plus System and the H200® Wireless Hand Rehabilitation System, both of which utilize functional electrical stimulation (FES). Patients may also benefit from the Vector Gait and Safety System®, a state-of-the-art, over-ground gait rehabilitation system that uses dynamic body weight support. Individual results vary. Consult with a qualified physician to determine if this product is right for you. Contraindications, Adverse Reactions and Precautions are available on-line at www.bioness.com

Additional information about Bioness can be found at www.bioness.com.