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BIONESS RECEIVES FIRST FDA CLEARANCE OF NEUROSTIMULATION SYSTEM FOR CHILDREN SUFFERING FROM FOOT DROP

L300 Foot Drop System Can Help Children with Cerebral Palsy, Stroke or Traumatic Brain Injury Regain Mobility and Lead More Independent Lives

Valencia, Calif. — January 22, 2013 —Bioness Inc. today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its L300® Foot Drop System to pediatric patients and their caregivers. This is the first FDA cleared neurostimulation device of this kind for use with children. The L300 is a neuromodulation technology designed to treat foot drop, a condition which causes walking difficulty in adults and pediatrics with upper motor neuron pathologies. Bioness will be showcasing the system and its use in pediatrics at the American Physical Therapy Association (APTA) conference this week in San Diego.

“More than 500,000 Americans suffer from the effects of cerebral palsy (CP), in addition to the large number of children affected by foot drop as a result of traumatic brain injury, stroke and other conditions. For these children, mobility can be a daily struggle, and result in having difficulty with many of the activities most of us consider essential to childhood,” said Dr. Michael Armento, pediatric physiatrist, [Children’s Specialized Hospital](#), the nation’s largest provider of pediatric rehabilitation services. “Having another potential intervention to offer children and families impacted by foot drop opens up the opportunity for us to not only promote physical development, but improve the independence of these children.”

“We are very excited to offer the L300 as the first neuromuscular stimulation device cleared by the FDA to benefit the thousands of children suffering with mobility issues as result of upper motor neuron injuries or diseases,” said Thomas G. Fogarty, President & CEO of Bioness. “Children who have traditionally relied on an orthosis or other compensatory aids now have a therapeutic treatment option that can help restore mobility and freedom in a non-invasive way. The L300 has helped thousands of adults regain mobility and now this same technology has the potential to provide pediatric patients with improved quality of life and a level of activity more closely associated with that of a child.”

Worn on the leg, the L300 has three main parts: a small wireless sensor in the shoe, a sport brace-like leg cuff worn just below the knee and a hand-held remote control. The three components use wireless communication to "talk" to each other. When an individual initiates a step, the L300 sends low-level electrical stimulation to the nerves in the lower leg which control the muscles responsible for lifting the foot. By lifting the foot at the appropriate time patients may walk with increased confidence, improved speed and reduced fatigue.

"Raising a child with mobility issues can be very challenging. You want your child to experience everything but they are constantly faced with obstacles and limitations," said Dayna Teske, mother of Daleney, a 12 year-old girl who has cerebral palsy and uses two Bioness L300 devices to help with mobility. "At first doctors didn't think Daleney would ever be able to walk, but with the help of the L300, Daleney has graduated from using a reverse Kaye walker to wearing only forearm crutches, giving her confidence to be more independent and active in our community. We're hopeful that more and more children and families will now be able to benefit from the L300."

The L300 Foot Drop System main use is by patients in the community. It can also be used for gait rehabilitation in inpatient or outpatient rehabilitation settings to potentially realize a variety of clinical benefits including improved mobility, maintaining or increasing range of motion, re-educating muscles, the prevention or slowing of muscle loss and increased local blood flow.

The pediatric L300 is now available for purchase. Individuals interested in more information can contact Bioness at 800-211-9136, Option 2.

About Bioness Inc.

Bioness develops and manufactures innovative, neuromodulation medical devices and distributes rehabilitative technologies that help improve lives and restore function for those living with neurological deficits and peripheral pain. The company's innovative neuromodulation products: the L300® Foot Drop System, L300® Plus System, H200® Hand Rehabilitation System and H200® Wireless Hand Rehabilitation System are cleared for use by the Food and Drug Administration and help individuals with central nervous system disorders such as stroke, multiple sclerosis, spinal cord injury, traumatic brain injury and cerebral palsy regain movement in affected limbs. Bioness also distributes the Dynavision D2 which is a rehabilitative technology designed to help patients achieve new levels of physical independence and productivity. Individual results vary. Consult with a qualified physician to find out if these products are right for you. Additional information about Bioness can be found at www.bioness.com.

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