Erchonia Submits Data to US FDA to Support Low-Level Laser 510(k) Market Clearance for Autism

Quadruple-Blind laser study proves success in treating Autism in children and adolescents.

The results are so strong, nobody can argue them.

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Erchonia, the World Leader in Low Level Laser technology, announces today that they have submitted data to the US FDA to support a 510(k) market clearance for Autism.

The clinical trial was a quadruple-blind (Participant, Care Provider, Investigator and Outcome Assessor), randomized, placebo-controlled, and crossover clinical trial. The study was designed to treat autistic children with the 640nm Erchonia Spectrum Laser as the active device or a 640nm LED or light emitting diode as a placebo device, which had the same power output. FDA input was obtained prior to clinical trial and implemented into the protocol.

Both test and placebo patients were treated twice a week for 4 weeks. Post-treatment follow-up on both sets of patients was performed after 4 weeks, 8 weeks, and 6 months. At the end of 6 months, patients from the LED placebo group were crossed over and then given Erchonia's Spectrum Laser treatment protocol. The results were documented and submitted to the US FDA for a 510(k) market clearance De Novo Application.

The inclusion criteria consisted of autistic children between the ages of 5 to 17 years old, and progress was measured by using the ABC or Aberrant Behavior Checklist as the primary diagnosis. The ABC 58-point symptom checklist was used to assess and classify behaviors of irritability and agitation; lethargy and social withdrawal, stereotypic behavior, hyperactivity and noncompliance, and inappropriate speech in children with developmental disorders. The ABC tests were performed at baseline, 2 weeks, and 4 weeks during the treatments phase, and 4 weeks, 8 weeks, and 6 months post-treatment in both the treated and placebo groups.

"This is a well-designed trial that shows evidence supporting the use of Low Level Laser Therapy in children and adolescents with autism," said Dr. Morales-Quezada, Associate Research Director at Spaulding-Labushagne Neuromodulation Center. "Moreover, the technique proved to be safe and well tolerated by the study participants. The active intervention showed to be more effective than the placebo (sham) device in treating symptoms of autistic disorder, and this statistically significant treatment effect was observed for all clinical outcomes, by the end of the intervention period and after

the 6 months follow-up. This evidence offers a new treatment option to be considered for children and adolescents with autism."

Calixto Machado, MD, PhD, FAAN, President of the Cuban Society of the Clinical Neurophysiology Institute of Neurology and Neurosurgery agreed, "Results are so strong, nobody can argue them."

Steven Shanks, President of Erchonia stated, "This study from a scientific perspective is one of the most stringent ways to perform a clinical trial. The original placebo patients have now acted as their own control group. The LED that was used as a placebo showed no results even though we used the same wavelength and power output."

The Erchonia Spectrum Laser implemented in this clinical trial was a prototype laser and is not currently sold. While waiting for the 510(k) market clearance, Erchonia will start the development process for the new Erchonia Spectrum Laser.

Erchonia would like to thank Calixto Machado, MD, PhD, FAAN, Mauricio Chinchilla, MD, Yanin Ferrer, MD, and the University of Havana for their dedication to research and helping Erchonia with its latest achievement.

About Erchonia. Erchonia created the low-level laser category in January 2002 when the FDA granted Erchonia the very 1st 510(k) market clearance for any low-level laser. This new study further sets Erchonia apart from its competitors based on their commitment to research and numerous 510(k) market clearances obtained through blind and controlled clinical trials.