Erchonia today announces the U.S. Food and Drug Administration (FDA) has granted the company 510 (k) clearance to market FX635, its new low level laser for the relief of chronic heel pain from plantar fasciitis. Clearance was based on a double-blind, randomized, multi-site and placebo-controlled clinical trial.

McKinney, TX (PRWEB) April 22, 2014

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After just two FX635 treatments a week for three weeks, patients treated with the FX635 Laser reported reduced pain on the VAS scale at 2 weeks, 6 months and 12 months post-treatment. On average, patients went from a 68 on the VAS scale down to 8 at the 12-month mark. Those patients who received a placebo laser did a not achieve a statistically-significant reduction in pain at any time during the clinical trial.

Michael Coughlin, MD, the clinical investigator, stated, “Erchonia’s FX635 low level laser for chronic plantar fasciitis demonstrated exceptional results with a marked reduction in almost all of the 30 treated patients. They had suffered from plantar fasciitis for an average of almost a year—one patient had pain for 5 years. All had undergone a variety of non-operative treatments which had all been unsuccessful. At the year follow-up point, almost all patients noted a dramatic reduction in pain and an improvement in function.”

Kerry Zang, DPM, added; “I use the Erchonia FX635 for chronic plantar fasciitis as part of a regenerative medicine protocol. This new technology is a breakthrough for chronic heel pain sufferers, because it offers pain-free treatment with no known side effects or contraindications. Low level laser technology works by stimulating a physiological response which is necessary to healing—whereas other treatments such as cortisone, suppresses inflammation which delays or even stops the healing process.”

Charlie Shanks, vice president of Erchonia, comments, “This FDA-clearance for the FX635 laser is Erchonia’s latest example of our ongoing commitment to low level laser technology research. Not only can it provide non-invasive relief to those who suffer from this type of chronic heel pain, the FX635 laser itself is extremely simple to operate and doesn’t require manual operation like all other pain management devices.”

The FDA has previously cleared Erchonia’s low level lasers for the reduction of chronic neck and shoulder pain; non-invasive reduction of cellulite, the non-invasive circumference reduction of the arms and the waist, hips and thighs; for liposuction and breast augmentation assistance and the reduction of associated pain; and for the treatment of acne.
For more information, please visit http://www.erchonia.com.

About Erchonia
Erchonia is the global leader in low level laser healthcare applications. Over the last 15 years, Erchonia has been conducting research and development with the world’s leading physicians to advance the science of low level lasers. Erchonia created the low level laser category after the company was granted the first low level laser FDA clearance for any indication in 2002. Prior to market introduction, all Erchonia lasers are proven safe and effective through independent clinical trials. Currently thousands of Erchonia’s lasers are used daily to reduce body fat and cellulite, eliminate pain, and treat acne. For additional information, visit http://www.erchonia.com