

# FDA Grants Market Clearance for Erchonia's Zerona Laser



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Proven safe and effective for circumference reduction of the waist, hips and thighs

**McKinney, TX August 30, 2010** – Erchonia Corporation, the world's leading manufacturer in low-level laser technology, has been granted market clearance by the U.S. Food and Drug Administration for the [non-invasive body contouring](#) device, the Zerona. The Zerona is the first non-invasive aesthetic device to receive FDA market clearance in the U.S. for circumferential reduction of the waist, hips, and thighs.

The FDA granted market clearance following the completion of a placebo-controlled, randomized, double-blind, multi-site clinical investigation evaluating sixty-seven study participants. The results obtained from that study demonstrated an average inch loss reduction of 3.65 inches across patient's waist, hips, and thighs in as little as two weeks. The clinical trial, absent of diet restrictions, exercise requirements, or any other adjunctive components properly illustrated the clinical utility of the Zerona and set the precedent on how aesthetic devices should be evaluated.

FDA clearance for [body contouring](#) is just the latest clearance in a long line for Erchonia's low-level laser devices having already earned FDA market clearances for breast augmentation (2008), acne (2005), liposuction (2004), and chronic pain (2001).

The [Zerona](#) emits a low-level, or cold, output energy that generates no thermal effect on the body's tissue eliminating any risk to the patient. Zerona has been clinically proven to target fat cells causing their immediate collapse thereby significantly reducing body volume. Through a natural process of fat removal, the laser-released fat is safely removed and broken down, providing patients with a truly non-invasive procedure without side effects or downtime.

"Zerona is scientifically-proven to be both safe and effective, and this most recent FDA clearance simply validates the research supporting this application," says Charlie Shanks, vice president of Erchonia. "Zerona's FDA clearance makes it even more unique in the marketplace and we are excited to continue the momentum with a new, integrated marketing campaign."

Having no predicate devices to base FDA clearance on, the Zerona had to undergo a review process called *de novo*, which is completed by the FDA in an average of 750 days. Erchonia submitted clinical data in August 2008 and was granted approval for safety and effectiveness nearly two years later.

[www.erchonia.asia](http://www.erchonia.asia)  
[contact@erchonia.asia](mailto:contact@erchonia.asia)  
+91-22-65151222