

K231474 Erchonia Violet ZERONA® Z6 OTCJul 21, 2023
60 days to decisionK231474 · Product code: **OLI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	May 22, 2023
Decision date	Jul 21, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Erchonia Corporation
Location	Fountain Inn, SC, US
Contact	Travis Sammons
Website	https://www.erchonia.com
510(k) history	26 submissions · 26 cleared · 2010-2026

Erchonia Corporation is a medical device manufacturer based in Fountain Inn, US, specializing in low-level laser technology for therapeutic applications. The company has received FDA 510(k) clearances from total submissions, with a regulatory track record spanning 2010 to 2026. Erchonia's cleared devices focus primarily on General & Plastic Surgery and Physical Medicine applications, including laser systems for pain management, fat loss, and tissue healing. The company remains actively engaged in FDA regulatory submissions, with its most recent clearance in 2026. Erchonia...

CLINICAL EVIDENCE - NCT05674292**An Evaluation of the Effect of the Erchonia Corporation Violet Zerona® Z6 for Body Contouring**

Status	Completed
Enrollment	25 patients (actual)
Study sites	2 sites
Condition studied	Circumference Reduction
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 28, 2023
Sponsor	Erchonia Corporation (Industry)

Primary outcome**Combined Circumference Reduction in Inches of the Waist, Hips, and Bilateral Thighs**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05674292