FDA 510(k) Premarket Notification

K251843 Erchonia EVRL

CLEARED

Sep 12, 2025
88 days to decision

K251843 · Product code: **OLP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251843/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Jun 16, 2025
Decision date	Sep 12, 2025
Days to decision	88 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...