FDA 510(k) Premarket Notification

K220519 Erchonia Zerona Z-Bed

CLEARED

Mar 24, 2022
29 days to decision

K220519 · Product code: **OLI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	Feb 23, 2022
Decision date	Mar 24, 2022
Days to decision	29 days
Third-party review	Yes
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...

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov