FDA 510(k) Premarket Notification

K180197 Erchonia FX-635

CLEARED

May 21, 2018
117 days to decision

K180197 · Product code: **NHN** · Physical Medicine
Source: https://www.510kdatabase.net/k180197/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Laser Non-thermal Instrument With Non-heating Effect For Adjunctive Use In Pain Therapy (NHN)
Date received	Jan 24, 2018
Decision date	May 21, 2018
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Erchonia Corporation**
Location	Fountain Inn, SC, US
Contact	Steven Shanks
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 Insight, Inc.**
Contact	Kevin Walls

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

CLINICAL EVIDENCE - NCT02538523

A Study to Evaluate the Effect of Low Level Laser Light on Low Back Pain

Status	Completed
Enrollment	58 patients (actual)
Study sites	3 sites
Condition studied	Low Back Pain
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Dec 10, 2017
Sponsor	Erchonia Corporation (Industry)

Primary outcome

Percentage of Participants Whose Change in Pain Rating on the Visual Analog Scale (VAS) Met the Individual Subject Success Criteria

Secondary outcome

Change in Total Score on the Oswestry Disability Index (ODI)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02538523