FDA 510(k) Premarket Notification

CLEARED

K212595 Erchonia FX-405

Nov 12, 2021
88 days to decision

K212595 · Product code: **NHN** · Physical Medicine
Source: https://www.510kdatabase.net/k212595/

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	Aug 16, 2021
Decision date	Nov 12, 2021
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	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...