

K251903 Erchonia DPN Laser (Model# EVRL)

Feb 19, 2026
244 days to decision

K251903 · Product code: **NHN** · Physical Medicine
Source: <https://www.510kdatabase.net/k251903/>

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	Jun 20, 2025
Decision date	Feb 19, 2026
Days to decision	244 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 - NCT05291975

Clinical Efficacy and Human Factors Validation Testing of the Erchonia EVRL for Providing Temporary Relief of Diabetic Peripheral Neuropathy Foot Pain

Status	Completed
Enrollment	64 patients (actual)
Study sites	4 sites
Condition studied	Neuropathy, Diabetic; Neuropathy;Peripheral; Neuropathy, Painful
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Dec 12, 2024
Sponsor	Erchonia Corporation (Industry)

Primary outcome

Number of Participants With a 30% or Greater Change in Pain Rating on the Visual Analog Scale (VAS)

Secondary outcome

Satisfaction With Study Outcome

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05291975

