FDA 510(k) Premarket Notification

K221987 Erchonia GVL

CLEARED

Sep 1, 2022
57 days to decision

K221987 · Product code: **NHN** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221987/

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	Jul 6, 2022
Decision date	Sep 1, 2022
Days to decision	57 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 - NCT00929305

Low Level Laser Light Therapy and Chronic Neck and Shoulder Pain

Status	Completed
Enrollment	100 patients (actual)
Condition studied	Shoulder Pain; Neck Pain; Musculoskeletal Pain; Musculoskeletal Strain; Musculoskeletal Sprain
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Jun 1, 2001
Sponsor	Erchonia Corporation (Industry)

Primary outcome

The Number of Participants Whose Self-reported Pain Rating in the Neck and Shoulder Area on the 0-100 Visual Analog Scale (VAS) Decreased by 30% or More From Baseline to One Day After Study Treatment

Secondary outcome

Range of Motion of the Neck and Shoulders

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT00929305