

**K191257 Erchonia EURL**Aug 8, 2019  
90 days to decisionK191257 · Product code: **NHN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k191257/>**SUBMISSION DETAILS**

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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	May 10, 2019
Decision date	Aug 8, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Erchonia Corporation</b>
Location	Fountain Inn, SC, US
Contact	Steven Shanks
Website	<a href="https://www.erchonia.com">https://www.erchonia.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k191257/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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