

**K162578 Zerona Z6 OTC**Dec 16, 2016  
92 days to decisionK162578 · Product code: **OLI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	Sep 15, 2016
Decision date	Dec 16, 2016
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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