FDA 510(k) Premarket Notification

# K243811 Erchonia Zerona® VZ8

**CLEARED**

Jan 10, 2025
30 days to decision

K243811 · Product code: **OLI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243811/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fat Reducing Low Level Laser (OLI) |
| Date received | Dec 11, 2024 |
| Decision date | Jan 10, 2025 |
| Days to decision | 30 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| 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...

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Regulatory Technology Services, LLC** |
| Contact | Prithul Bom |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243811/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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