

K121690 ETCHONIA ZERONA ARMSAug 23, 2012
77 days to decisionK121690 · Product code: **OLI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k121690/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fat Reducing Low Level Laser (OLI) |
| Date received | Jun 7, 2012 |
| Decision date | Aug 23, 2012 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Erchonia Corporation |
| Location | Fountain Inn, SC, US |
| Contact | Kevin Walls |
| Website | https://www.erschonia.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...
