

**K100509 THL1 LASER**Jun 8, 2010  
106 days to decisionK100509 · Product code: **NHN** · Physical Medicine  
Source: <https://www.510kdatabase.net/k100509/>**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         | Feb 22, 2010  |
| Decision date         | Jun 8, 2010   |
| Days to decision      | 106 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Erchonia Corporation</b>                                       |
| Location       | Fountain Inn, SC, US  |
| Contact        | Kevin Walls   |
| 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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