

**K251298 Mobile Laser Unit (1001-N2)**Sep 4, 2025  
129 days to decisionK251298 · Product code: **ONO** · Neurology  
Source: <https://www.510kdatabase.net/k251298/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Laser With Mr Thermography (ONO)
Date received	Apr 28, 2025
Decision date	Sep 4, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Thermoguide Workstation (1100-N1); Laser Applicator (4012-N5, 4017-N2, 4017-N4); MR Introducer (4013-N6)

**APPLICANT**

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Company	<b>Clinical Laserthermia Systems, AB</b>
Location	Lund, SE
Contact	Dan Mogren
510(k) history	6 submissions · 6 cleared · 2015-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Omedtech, LLC</b>
Contact	David Makanani

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

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