

K214125 TRANBERG Thermoguide Therapy SystemSep 22, 2022
266 days to decisionK214125 · Product code: **ONO** · Neurology
Source: <https://www.510kdatabase.net/k214125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Laser With Mr Thermography (ONO)
Date received	Dec 30, 2021
Decision date	Sep 22, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John Smith

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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