

**K250307 Visualase V2 MRI-guided Laser Ablation System  
(9736422)**May 29, 2025  
115 days to decisionK250307 · Product code: **ONO** · Neurology  
Source: <https://www.510kdatabase.net/k250307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Laser With Mr Thermography (ONO)
Date received	Feb 3, 2025
Decision date	May 29, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Navigation</b>
Location	Louisville, CO, US
Contact	Sharon McDermott
510(k) history	9 submissions · 9 cleared · 2017-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250307/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026