

**K211269 Visualase MRI-Guided Laser Ablation System (SW 3.4)**Jan 7, 2022  
255 days to decisionK211269 · Product code: **ONO** · Neurology  
Source: <https://www.510kdatabase.net/k211269/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Laser With Mr Thermography (ONO)
Date received	Apr 27, 2021
Decision date	Jan 7, 2022
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Navigation, Inc.</b>
Location	Lafayette, CO, US
Contact	Sharon McDermott
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
510(k) history	35 submissions · 35 cleared · 2005-2026

Medtronic Navigation, Inc. is based in Lafayette, US. The company specializes in surgical navigation and imaging systems for minimally invasive procedures. The company has received FDA 510(k) clearances from total submissions since 2005. Neurology devices represent a dominant category, including cranial and laser ablation systems. The latest clearance in 2026 reflects continued regulatory activity and product innovation. Recent cleared devices span multiple surgical specialties. StealthStation and Stealth AXiS™ platforms serve neurology, orthopedic, and ear, nose, and thr...