

K253391 Visualase Cooled Laser Applicator System (9735559)Mar 13, 2026
164 days to decisionK253391 · Product code: **ONO** · Neurology
Source: <https://www.510kdatabase.net/k253391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Laser With Mr Thermography (ONO)
Date received	Sep 30, 2025
Decision date	Mar 13, 2026
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Visualase Cooled Laser Applicator System (9735560); Visualase Cooled Laser Applicator System (9735561)

APPLICANT

Company	Medtronic Navigation, Inc.
Location	Lafayette, CO, US
Contact	Sharon McDermott
Website	https://www.medtronic.com
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...