

**K201189 Stealthstation S8 Spine Software v1.3.0**May 29, 2020  
28 days to decisionK201189 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k201189/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 1, 2020
Decision date	May 29, 2020
Days to decision	28 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	Jason Woehrle
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...