

**K153660 StealthStation System with Cranial Software**Sep 14, 2016  
268 days to decisionK153660 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k153660/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 21, 2015
Decision date	Sep 14, 2016
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Navigation, Inc.</b>
Location	Lafayette, CO, US
Contact	Augusta Henao
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...

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