

# K162655 StealthConnect Remote Viewing, Planning and Collaboration System

Apr 21, 2017  
210 days to decisionK162655 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k162655/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 23, 2016
Decision date	Apr 21, 2017
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

---

Company	<b>Medtronic Navigation, Inc.</b>
Location	Lafayette, CO, US
Contact	MONICA R. MONTANEZ
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...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162655/> 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 June 1, 2026