

**K061248 AXIEM IMAGELESS HIP MODULE FOR THE STEALTHSTATION SYSTEM**Aug 31, 2006  
120 days to decisionK061248 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k061248/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	May 3, 2006
Decision date	Aug 31, 2006
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medtronic Navigation, Inc.</b>
Location	Lafayette, CO, US
Contact	TINA DREILING
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/k061248/> 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 28, 2026