

K162309 StealthStation S8 System Platforms and StealthStation Cranial Software

Mar 31, 2017
226 days to decisionK162309 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k162309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 17, 2016
Decision date	Mar 31, 2017
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Navigation, Inc.
Location	Lafayette, CO, US
Contact	Tia Fushimi-Bain
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...

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Device record: <https://www.510kdatabase.net/k162309/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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