FDA 510(k) Premarket Notification

K253379 Stealth AXiS Cranial clinical application

CLEARED

Mar 26, 2026
177 days to decision

K253379 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k253379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 30, 2025
Decision date	Mar 26, 2026
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Navigation, Inc.**
Location	Lafayette, CO, US
Contact	Victoria Baldock
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...