

K231976 StealthStation Cranial Software, v3.1.5 (9735585)Oct 19, 2023
108 days to decisionK231976 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k231976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 3, 2023
Decision date	Oct 19, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Navigation, Inc.
Location	Lafayette, CO, US
Contact	Rishi Mehta
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...