FDA 510(k) Premarket Notification

CLEARED

K253381 Stealth AXiS™ Surgical System with Stealth AXiS™ Spine clinical application

Feb 12, 2026
135 days to decision

K253381 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k253381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 30, 2025
Decision date	Feb 12, 2026
Days to decision	135 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...