

K130608 QUADCUTAug 7, 2013
153 days to decisionK130608 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k130608/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received | Mar 7, 2013 |
| Decision date | Aug 7, 2013 |
| Days to decision | 153 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Navigation, Inc. |
| Location | Lafayette, CO, US |
| Contact | SHARON MCDERMOTT |
| 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...
