

**K012938 SMITH & NEPHEW IMAGE GUIDED SURGICAL INSTRUMENTS FOR KNEE APPLICATIONS**Feb 8, 2002  
161 days to decisionK012938 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k012938/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 31, 2001
Decision date	Feb 8, 2002
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Smith &amp; Nephew, Inc.</b>
Location	McHenry, IL, US
Contact	TRUDE C NAFF
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...