

**K083565 PIGALILEO TOTAL HIP REPLACEMENT (THR)
SOFTWARE APPLICATION V3.0**Feb 20, 2009
79 days to decisionK083565 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k083565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 3, 2008
Decision date	Feb 20, 2009
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	GINO ROUSS
Website	http://www.smith-nephew.com/
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...

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Device record: <https://www.510kdatabase.net/k083565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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