FDA 510(k) Premarket Notification

K082267 PIGALILEO CAS, VERSION 4.0 AND TKR BASE, VERSION 2.1

CLEARED

Oct 29, 2008
79 days to decision

K082267 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k082267/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 11, 2008
Decision date	Oct 29, 2008
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	RISHI SINHA
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k082267/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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