FDA 510(k) Premarket Notification

CLEARED

K011985 SMITH & NEPHEW PHOENIX 5.0 ALLOGRAFT ANCHOR KIT

Nov 2, 2001
129 days to decision

K011985 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k011985/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jun 26, 2001
Decision date	Nov 2, 2001
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	TIM CRABTREE
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...