FDA 510(k) Premarket Notification

CLEARED

K123579 FOOTPRINT ULTRA PK4.5MM AND 5.5MM SUTURE ANCHOR, SL

Jan 23, 2013
65 days to decision

K123579 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k123579/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 19, 2012
Decision date	Jan 23, 2013
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	CATHERINE KILSHAW
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...