FDA 510(k) Premarket Notification

CLEARED

K101459 OSTEORAPTOR II SUTURE ANCHOR OR TO BE DETERMINED MODEL: 72202764 72202765 72202766 72202767 72202768 72202769 72202770

Jan 27, 2011
246 days to decision

K101459 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k101459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 26, 2010
Decision date	Jan 27, 2011
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	JULIE ACKER
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/k101459/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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