

K151105 Smith and Nephew Suture Anchors - 5.0mm Absorbable Polymer Anchor, Smith and Nephew Suture Anchors - TAG Bioraptor Suture Anchor 7209317, 7209318, Smith and Nephew Suture Anchors - Bioraptor 2.3 PK Suture Anchor, Smith and Nephew Suture Anchors - Osteoraptor Suture Anchor, Smith and Nephew Suture Anchors - Twinfix Ultra HA Suture Anchor, Smith and Nephew Suture Anchors - OSTEORAPTOR Curved Suture Anchors, Smith and Nephew Suture Anchors - Ultra Fast-Fix Meniscal Repair System, Ultra Fa

Jul 28, 2015
95 days to decision

K151105 · Product code: MAI · Orthopedic
Source: <https://www.510kdatabase.net/k151105/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Apr 24, 2015
Decision date	Jul 28, 2015
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	McHenry, IL, US
Contact	Katherine Marcaccio
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...