CLEARED

Dec 2, 2015
84 days to decision

K152566 PEBA Anchor/Suture Combination, 2.0mm Mini-Tac Anchor, Model 10-1629-01, Modification to Twinfix Ti Quick-T, Twinfix FT PK, Twinfix Ultra Ti, Twinfix Ultra PK, Twinfix Ultra HA Suture Anchors, FOOTPRINT Ultra OK Suture Anchors, BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor, HEALICOIL PK Suture Anchor (formerly Next Generation Fully Threaded Suture Anchor), Bioraptor Curved 2.3 PK Suture Anchors

K152566 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k152566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 9, 2015
Decision date	Dec 2, 2015
Days to decision	84 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...