FDA 510(k) Premarket Notification

CLEARED

K233730 Footprint Mini PK, 3.5mm Suture Anchor

Jan 17, 2024
57 days to decision

K233730 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k233730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 21, 2023
Decision date	Jan 17, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew**
Location	Memphis, TN, US
Contact	Catherine Phelan
Website	http://www.smith-nephew.com/
510(k) history	17 submissions · 17 cleared · 2015-2025

Smith & Nephew is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in Memphis, US, and serves approximately 100 countries worldwide. The company has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent the dominant category, including pelvic and acetabular systems, patella plates, suture anchors, cable systems, external fixators, arthroscopes, and limb lengthening systems. The latest clearance was granted in 2025, confirming a...