CLEARED

K213126 Smith & Nephew, Inc. Plates and Screws Systems: EVOS, Peri-Loc, D-Rad, TC-100, VLP Mini-Mod, Compression Hip Screw (CHS), CONQUEST FN, and cannulated screws

Sep 29, 2022
367 days to decision

K213126 · Product code: **JDO** · Orthopedic
Source: https://www.510kdatabase.net/k213126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fixation, Proximal Femoral, Implant (JDO)
Date received	Sep 27, 2021
Decision date	Sep 29, 2022
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	Thomas Fearnley
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...