

K180277 Smith & Nephew SURESHOT Distal Targeting System V4.0 Targeter

Apr 24, 2018
83 days to decision

K180277 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k180277/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 31, 2018
Decision date	Apr 24, 2018
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Allison Chan
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...