

K201253 Modular Rail System, TAYLOR SPATIAL FRAME External Fixator, JET-X Fixator, ILIZAROV External Fixator, Other External Fixation

Dec 8, 2020
211 days to decision

K201253 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k201253/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	May 11, 2020
Decision date	Dec 8, 2020
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew
Location	Memphis, TN, US
Contact	Konrad Wolfmeyer
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...