

K163653 NOVOS-NAIL Limb Lengthening System (LLS)Oct 13, 2017
294 days to decisionK163653 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k163653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Dec 23, 2016
Decision date	Oct 13, 2017
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew
Location	Memphis, TN, US
Contact	Allison Chan
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...
