

K250623 Pediatric Nailing Platform Tibia Pediatric Nailing Platform Femur

Apr 1, 2025
29 days to decision

K250623 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k250623/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Mar 3, 2025
Decision date	Apr 1, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatrics Corp.
Location	Warsaw, IN, US
Contact	Yan Li
Website	https://www.orthopediatrics.com
510(k) history	40 submissions · 38 cleared · 2008-2026

OrthoPediatrics Corp. is a pediatric orthopedic medical device company focused exclusively on children’s orthopedic care. Based in Warsaw, Indiana, the company designs and manufactures implants and surgical systems for pediatric trauma, deformity correction, scoliosis, and sports medicine applications. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. 100% of submissions fall within the Orthopedic device category. The latest clearance in 2026 reflects continued regulatory activity and product innovation in pediatric o...