

**K190321 Pediatric Nailing PlatformFemur**Oct 9, 2019  
238 days to decisionK190321 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k190321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 13, 2019
Decision date	Oct 9, 2019
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrthoPediatics Corp.</b>
Location	Warsaw, IN, US
Contact	Jen Gregory
Website	<a href="https://www.orthopediatrics.com">https://www.orthopediatrics.com</a>
510(k) history	40 submissions · 38 cleared · 2008-2026

OrthoPediatics 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...

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