

**K083726 PEDINAIL INTRAMEDULLARY NAILING SYSTEM**Mar 11, 2009  
86 days to decisionK083726 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k083726/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Dec 15, 2008
Decision date	Mar 11, 2009
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrthoPediatics Corp.</b>
Location	Warsaw, IN, US
Contact	GARY BARNETT
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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