

**K201838 PediFlex Flexible Nail System**Jan 29, 2021  
211 days to decisionK201838 · Product code: **HTY** · Orthopedic  
Source: <https://www.510kdatabase.net/k201838/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Jul 2, 2020
Decision date	Jan 29, 2021
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrthoPediatrics Corp.</b>
Location	Warsaw, IN, US
Contact	Yan Li
Website	<a href="https://www.orthopediatrics.com">https://www.orthopediatrics.com</a>
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...