

**K190324 OrthoPediatrics Cannulated Screw System**Jul 5, 2019  
142 days to decisionK190324 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k190324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 13, 2019
Decision date	Jul 5, 2019
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrthoPediatrics 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

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...

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