

**K120291 OP SPINE SYSTEM**Apr 16, 2012  
76 days to decisionK120291 · Product code: **OSH** · Orthopedic  
Source: <https://www.510kdatabase.net/k120291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Jan 31, 2012
Decision date	Apr 16, 2012
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrthoPediatics Corp.</b>
Location	Warsaw, IN, US
Contact	MARK FOX
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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