

# K162307 OrthoPediatrics Locking Proximal Femur System Cortical Screws

Sep 27, 2016  
41 days to decisionK162307 · Product code: HRS · Orthopedic  
Source: <https://www.510kdatabase.net/k162307/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 17, 2016
Decision date	Sep 27, 2016
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>OrthoPediatrics Corp.</b>
Location	Warsaw, IN, US
Contact	ADAM CARGILL
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162307/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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