

K190992 OrthoPediatrics PediFoot Deformity Corrections System

Aug 6, 2019
113 days to decisionK190992 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k190992/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 15, 2019
Decision date	Aug 6, 2019
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatrics Corp.
Location	Warsaw, IN, US
Contact	Jen Gregory
Website	https://www.orthopediatrics.com
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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Device record: <https://www.510kdatabase.net/k190992/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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