

K121250 OP SPINE SYSTEMJun 19, 2012
55 days to decisionK121250 · Product code: **OSH** · Orthopedic
Source: <https://www.510kdatabase.net/k121250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Apr 25, 2012
Decision date	Jun 19, 2012
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatics Corp.
Location	Warsaw, IN, US
Contact	MARK FOX
Website	https://www.orthopediatrics.com
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...
