

K222105 RESPONSE 5.5/6.0 Cannulated Screw SystemMar 23, 2023
248 days to decisionK222105 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k222105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 18, 2022
Decision date	Mar 23, 2023
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatrics Corp.
Location	Warsaw, IN, US
Contact	Jennifer 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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