

K193100 RESPONSE™ Spine System, RESPONSE™ 4.5/5.0 Spine System, RESPONSE™ 5.5/6.0 Spine SystemMar 24, 2020
137 days to decisionK193100 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k193100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 8, 2019
Decision date	Mar 24, 2020
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatrics Corp.
Location	Warsaw, IN, US
Contact	Jackie Jaskula
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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