FDA 510(k) Premarket Notification

CLEARED

K181390 Response Spine System, Response 5.5/6.0 Spine System, Response 4.5/5.0 Spine System

Sep 18, 2018
112 days to decision

K181390 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k181390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 29, 2018
Decision date	Sep 18, 2018
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**OrthoPediatrics Corp.**
Location	Warsaw, IN, US
Contact	Mark Fox
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...