

K200303 Reform Pedicle Screw SystemMay 19, 2020
103 days to decisionK200303 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k200303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 6, 2020
Decision date	May 19, 2020
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Spine
Location	Pear, MS, US
Contact	Micheal C. Dawson
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	The OrthoMedix Group, Inc.
Contact	John D. Webb

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200303/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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