

K192930 Dymaxeon Spine SystemMay 12, 2020
208 days to decisionK192930 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k192930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 17, 2019
Decision date	May 12, 2020
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Back 2 Basics Direct, LLC
Location	Independence, OH, US
Contact	Lou Keppler
510(k) history	4 submissions · 4 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	Backroads Consulting
Contact	Karen E Warden

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

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