FDA 510(k) Premarket Notification

K192930 Dymaxeon Spine System

CLEARED

May 12, 2020
208 days to decision

K192930 · 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