

K170989 Dymaxeon Spine SystemMay 22, 2017
49 days to decisionK170989 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k170989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 3, 2017
Decision date	May 22, 2017
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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