

**K150184 Dymaxeon Spine System**Jun 15, 2015  
139 days to decisionK150184 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k150184/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 27, 2015
Decision date	Jun 15, 2015
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Back 2 Basics Direct, LLC</b>
Location	Independence, OH, US
Contact	Scot Miller
510(k) history	4 submissions · 4 cleared · 2015-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150184/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026