

**K180153 X-spine Cortical Bone Screw System**Mar 15, 2018  
55 days to decisionK180153 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k180153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 19, 2018
Decision date	Mar 15, 2018
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X-Spine Systems, Inc.</b>
Location	Centerville, OH, US
Contact	Charlene Brumbaugh
510(k) history	34 submissions · 34 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180153/> 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 May 16, 2026