

**K120832 FORTEX PEDICLE SCREW SYSTEM**Oct 23, 2012  
218 days to decisionK120832 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k120832/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 19, 2012
Decision date	Oct 23, 2012
Days to decision	218 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	DAVID KIRSCHMAN
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/k120832/> 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 18, 2026