

**K121172 REFORM PEDICLE SCREW SYSTEM**Aug 8, 2012  
113 days to decisionK121172 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k121172/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Apr 17, 2012
Decision date	Aug 8, 2012
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinal USA</b>
Location	Brandon, MS, US
Contact	J.D. WEBB
510(k) history	23 submissions · 23 cleared · 2006-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121172/> 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 17, 2026