

**K062136 PASS 2 SPINAL SYSTEM**Oct 6, 2006  
72 days to decisionK062136 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k062136/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 26, 2006
Decision date	Oct 6, 2006
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea</b>
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	4 submissions · 4 cleared · 2003-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062136/> 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 19, 2026