

**K150049 PASS LP Spinal System**Feb 10, 2015  
29 days to decisionK150049 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k150049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jan 12, 2015
Decision date	Feb 10, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International</b>
Location	Round Rock, TX, US
Contact	Audrey Vion
510(k) history	17 submissions · 16 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150049/> 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 27, 2026