

**K012175 PASS SPINAL SYSTEM**Jul 31, 2001  
19 days to decisionK012175 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k012175/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 12, 2001
Decision date	Jul 31, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Encore Orthopedics, Inc.</b>
Location	Red Rock, TX, US
Contact	JOANNA DROEGE
510(k) history	85 submissions · 74 cleared · 1993-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012175/> 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 20, 2026