

**K023644 MODIFICATION TO INCOMPASS SPINAL FIXATION SYSTEM**Nov 25, 2002  
26 days to decisionK023644 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k023644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Oct 30, 2002
Decision date	Nov 25, 2002
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinal Concepts, Inc.</b>
Location	Austin, TX, US
Contact	AUDREY SWEARINGEN
510(k) history	33 submissions · 28 cleared · 1997-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023644/>; 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