

**K062853 MODIFICATION TO STRYKER SPINE OASYS SYSTEM**Oct 24, 2006  
29 days to decisionK062853 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k062853/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 25, 2006
Decision date	Oct 24, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Spine</b>
Location	Allendale, NJ, US
Contact	SIMONA VOIC
510(k) history	74 submissions · 73 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062853/> 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