

**K070573 SYNAPSE SYSTEM**Jun 8, 2007  
100 days to decisionK070573 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k070573/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 28, 2007
Decision date	Jun 8, 2007
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes Spine Co.Lp</b>
Location	West Chester, PA, US
Contact	SUSAN LEWANDOWSKI
510(k) history	18 submissions · 18 cleared · 2005-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070573/> 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 18, 2026