

**K113044 SYNTHES MIRS**Dec 21, 2011  
70 days to decisionK113044 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k113044/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 12, 2011
Decision date	Dec 21, 2011
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes Spine</b>
Location	Paoli, PA, US
Contact	HEATHER GUERIN
510(k) history	36 submissions · 32 cleared · 1995-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113044/> 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