

**K111048 SYNTHES SCOUT TACK FIXATION**Jun 14, 2012  
426 days to decisionK111048 · Product code: **OMR** · Orthopedic  
Source: <https://www.510kdatabase.net/k111048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Vessel Guard Or Cover (OMR)
Date received	Apr 15, 2011
Decision date	Jun 14, 2012
Days to decision	426 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/k111048/> 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