

**K092464 SPINEOLOGY FACET SCREW**Nov 9, 2009  
90 days to decisionK092464 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k092464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Aug 11, 2009
Decision date	Nov 9, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineology, Inc.</b>
Location	Stillwater, MN, US
Contact	Karen Roche
510(k) history	54 submissions · 51 cleared · 1999-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092464/> 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