

**K123932 ZYGAFIX SPINAL FACET SCREW SYSTEM**May 1, 2013  
132 days to decisionK123932 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k123932/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Dec 20, 2012
Decision date	May 1, 2013
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>X-Spine Systems, Inc.</b>
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN
510(k) history	34 submissions · 34 cleared · 2005-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123932/> 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