

**K131951 IRIX-C CERVICAL INTEGRATED FUSION SYSTEM**Aug 14, 2013  
48 days to decisionK131951 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k131951/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 27, 2013
Decision date	Aug 14, 2013
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131951/> 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 17, 2026