

**K151934 ROI-C Titanium-Coated Implant System**Dec 7, 2015  
146 days to decisionK151934 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k151934/>**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	Jul 14, 2015
Decision date	Dec 7, 2015
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ldr Spine USA</b>
Location	Austin, TX, US
Contact	JAMES WILSON
510(k) history	25 submissions · 25 cleared · 2005-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151934/> 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