

**K082262 LDR SPINE ROI INTERBODY FUSION SYSTEM**Feb 2, 2009  
178 days to decisionK082262 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k082262/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 8, 2008
Decision date	Feb 2, 2009
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ldr Spine USA</b>
Location	Austin, TX, US
Contact	NOEL BARTSCH
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/k082262/> 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