

**K043349 OPEN RADIOTRSPARENT INTERSOMATIC  
IMPLANT (ROI)**Jun 29, 2005  
205 days to decisionK043349 · Product code: **MQP** · Orthopedic  
Source: <https://www.510kdatabase.net/k043349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Dec 6, 2004
Decision date	Jun 29, 2005
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ldr Spine USA</b>
Location	Austin, TX, US
Contact	BRAIN BURKINSHAW
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/k043349/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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