

**K113561 TM ARDIS INTERBODY SYSTEM TM ARDIS  
INTERBODY SYSTEM INSTRUMENTATION**May 29, 2012  
180 days to decisionK113561 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k113561/>**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	Dec 1, 2011
Decision date	May 29, 2012
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer Trabecular Metal Technology</b>
Location	Parsippany, NJ, US
Contact	JUDITH ROSEN
510(k) history	11 submissions · 11 cleared · 2007-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113561/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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