

**K123602 TM ARDIS INTERBODY SYSTEM INSERTER**Mar 1, 2013  
100 days to decisionK123602 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k123602/>**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	Nov 21, 2012
Decision date	Mar 1, 2013
Days to decision	100 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/k123602/> 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