

**K112986 LATERAL FUSION DEVICE**May 1, 2012  
208 days to decisionK112986 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k112986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 6, 2011
Decision date	May 1, 2012
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integra Spine (Integra Lifesciences)</b>
Location	Medina, OH, US
Contact	DALE DAVISON
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112986/> 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 18, 2026