

**K143143 PATHWAY ELIF**Jul 22, 2015  
261 days to decisionK143143 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k143143/>**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 3, 2014
Decision date	Jul 22, 2015
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Custom Spine, Inc.</b>
Location	Conway, NH, US
Contact	Mahmoud Abdelgany
510(k) history	12 submissions · 12 cleared · 2005-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143143/> 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