

**K151581 Leva Spacer System**Jul 9, 2015  
28 days to decisionK151581 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k151581/>**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	Jun 11, 2015
Decision date	Jul 9, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spine Wave, Inc.</b>
Location	Shelton, CT, US
Contact	GAIL YAEKER-DAUNIS
510(k) history	57 submissions · 57 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151581/> 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