

**K152620 Spine Wave Gen II Expandable Interbody System**Jan 15, 2016  
123 days to decisionK152620 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k152620/>**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	Sep 14, 2015
Decision date	Jan 15, 2016
Days to decision	123 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/k152620/> 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