

**K160291 Optimus ALIF System**Feb 18, 2016  
15 days to decisionK160291 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k160291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Feb 3, 2016
Decision date	Feb 18, 2016
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amendia, Inc.</b>
Location	Apple Valley, MN, US
Contact	Kristen Allen
510(k) history	16 submissions · 16 cleared · 2009-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160291/> 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 14, 2026