

**K160924 Amendia Interbody Fusion Devices**Nov 8, 2016  
218 days to decisionK160924 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k160924/>**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	Apr 4, 2016
Decision date	Nov 8, 2016
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amendia, Inc.</b>
Location	Apple Valley, MN, US
Contact	Bruce Hooper
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/k160924/> 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