

**K162236 Ax Stand-Alone ALIF System**Apr 20, 2017  
254 days to decisionK162236 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k162236/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 9, 2016
Decision date	Apr 20, 2017
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasis, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Marshall McCarty
510(k) history	33 submissions · 32 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162236/> 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 16, 2026