

**K182139 AXTi Titanium Stand-Alone ALIF System**Jun 21, 2019  
318 days to decisionK182139 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k182139/>**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 7, 2018
Decision date	Jun 21, 2019
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	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/k182139/> 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 June 28, 2026