

K250603 AxTiHA® Stand-Alone ALIF SystemMar 24, 2025
24 days to decisionK250603 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k250603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Feb 28, 2025
Decision date	Mar 24, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis
Location	Salt Lake City, UT, US
Contact	Mr. Mike Thomas
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250603/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026