

K212967 AxTiHA Stand-Alone ALIF SystemOct 15, 2021
29 days to decisionK212967 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k212967/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Sep 16, 2021 |
| Decision date | Oct 15, 2021 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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