FDA 510(k) Premarket Notification

K182139 AXTi Titanium Stand-Alone ALIF System

CLEARED

Jun 21, 2019
318 days to decision

K182139 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k182139/

SUBMISSION DETAILS

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

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