

K201671 A-Link ZMay 4, 2021
319 days to decisionK201671 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k201671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jun 19, 2020
Decision date	May 4, 2021
Days to decision	319 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acuity Surgical Devices, LLC
Location	Irving, TX, US
Contact	Bryan Cowan
Website	https://acuitysurgical.com
510(k) history	8 submissions · 8 cleared · 2021-2025

Acuity Surgical Devices, LLC develops spinal implant solutions for surgeons and patients. Based in Irving, Texas, the company delivers complete systems for lumbar, cervical, and biologic spine surgery since 2013. The company has received FDA 510(k) clearances from total submissions, all in Orthopedic devices. Clearances span 2021 to 2025, demonstrating sustained regulatory activity and market presence in spinal implant technology. Acuity's product portfolio includes stand-alone anterior lumbar fusion systems, modular cervical fixation platforms, posterior lumbar interbody...

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Lucie Dalet

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k201671/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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