

**K241413 sagAlign Lumbar Cage System (Various PNs)**Jul 17, 2024  
61 days to decisionK241413 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k241413/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 17, 2024
Decision date	Jul 17, 2024
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acuity Surgical Devices, LLC</b>
Location	Irving, TX, US
Contact	Chuck Forton
Website	<a href="https://acuitysurgical.com">https://acuitysurgical.com</a>
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...