FDA 510(k) Premarket Notification

**CLEARED**

# K221535 Align Lumbar Interbody Fusion System

Jul 22, 2022
56 days to decision

K221535 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221535/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | May 27, 2022 |
| Decision date | Jul 22, 2022 |
| Days to decision | 56 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...