FDA 510(k) Premarket Notification

CLEARED

K230639 Align Cervical Interbody Fusion System

Dec 1, 2023
268 days to decision

K230639 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k230639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 8, 2023
Decision date	Dec 1, 2023
Days to decision	268 days
Third-party review	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...