FDA 510(k) Premarket Notification

K221936 Standalone ALIF Interbody Fusion System

CLEARED

Oct 17, 2022
108 days to decision

K221936 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k221936/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 1, 2022
Decision date	Oct 17, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eminent Spine**
Location	Leander, TX, US
Contact	Stephen Courtney
510(k) history	11 submissions · 11 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Daniel Johnson

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