FDA 510(k) Premarket Notification

K252610 ZSFab Lumbar Interbody System

CLEARED

Nov 25, 2025
99 days to decision

K252610 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k252610/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 18, 2025
Decision date	Nov 25, 2025
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zsfab, Inc.**
Location	Cambridge, MA, US
Contact	Sijin Ren
510(k) history	5 submissions · 5 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Applied Technical Services (Empirical Technologies)**
Contact	Nathan Wright

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