FDA 510(k) Premarket Notification

CLEARED

K221858 ZSFab Lumbar Interbody System

Oct 14, 2022
109 days to decision

K221858 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221858/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 27, 2022
Decision date	Oct 14, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zsfab, Inc.**
Location	Cambridge, MA, US
Contact	Xuewei Ma
Website	https://www.zsfab.com/
510(k) history	5 submissions · 5 cleared · 2021-2026

Zsfab, Inc. develops patient-specific spinal implants using advanced design and digitally structured materials. The company is based in Cambridge with a focus on personalized orthopedic solutions for spine surgery. Zsfab has received FDA 510(k) clearances from total submissions since its first clearance in 2021. The company specializes exclusively in orthopedic devices, with recent cleared products including cervical and lumbar interbody systems. Latest clearance activity in 2026 confirms the company remains actively engaged in regulatory submissions. Zsfab's implant desi...

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E Warden

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221858/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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