FDA 510(k) Premarket Notification

K202488 ZSFab Cervical Interbody System

CLEARED

Jan 7, 2021
129 days to decision

K202488 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k202488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 31, 2020
Decision date	Jan 7, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zsfab, Inc.**
Location	Cambridge, MA, US
Contact	Kai Xu
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