

K232150 ZSFab Cervical Interbody SystemAug 18, 2023
30 days to decisionK232150 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k232150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 19, 2023
Decision date	Aug 18, 2023
Days to decision	30 days
Third-party review	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...