

K261451 ZSAlign Cervical Interbody System

Jul 31, 2026
91 days to decision

K261451 · Product code: OVE · Orthopedic
Source: <https://www.510kdatabase.net/k261451/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 1, 2026
Decision date	Jul 31, 2026
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zsfab, Inc.
Location	Cambridge, MA, US
Contact	David Ma
Website	https://www.zsfab.com/
510(k) history	6 submissions · 6 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...