

K260549 ZSFab Cervical Interbody System and ZSFab Lumbar Interbody System

Apr 24, 2026
65 days to decision

K260549 · Product code: ODP · Orthopedic
Source: <https://www.510kdatabase.net/k260549/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 18, 2026
Decision date	Apr 24, 2026
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zsfab, Inc.
Location	Cambridge, MA, US
Contact	Yuanqiao Wu
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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k260549/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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