

K242734 ZSFab Cervical Interbody SystemNov 7, 2024
58 days to decisionK242734 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k242734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 10, 2024
Decision date	Nov 7, 2024
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ZSFab Lumbar Interbody System

APPLICANT

Company	Zsfab
Location	Waltham, MA, US
Contact	Yuanqiao Wu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	MRC Global
Contact	Danielle Besal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242734/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026