FDA 510(k) Premarket Notification

K242734 ZSFab Cervical Interbody System

CLEARED

Nov 7, 2024
58 days to decision

K242734 · 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	Walthan, 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