FDA 510(k) Premarket Notification

CLEARED

K252219 Cervical Interbody and VBR Fusion System

Jan 14, 2026
183 days to decision

K252219 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k252219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 15, 2025
Decision date	Jan 14, 2026
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sync Surgical**
Location	Plano, TX, US
Contact	Shawn Culbertson
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Djj Consulting, LLC**
Contact	Daniel Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov