

K251431 FIX-C PEEK ACIF SA SystemJun 27, 2025
50 days to decisionK251431 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k251431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 8, 2025
Decision date	Jun 27, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jeil Medical Corporation
Location	Deer Field, IL, US
Contact	Jinwoo Kim
510(k) history	53 submissions · 53 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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