

K242517 ProAM ACDF SystemNov 20, 2024
89 days to decisionK242517 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k242517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 23, 2024
Decision date	Nov 20, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pro Surgical, Inc.
Location	Encinitas, CA, US
Contact	Jason Blain
510(k) history	3 submissions · 3 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242517/> 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