FDA 510(k) Premarket Notification

K242517 ProAM ACDF System

CLEARED

Nov 20, 2024
89 days to decision

K242517 · 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