

K212358 Romero Cervical CageJan 10, 2022
165 days to decisionK212358 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k212358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jul 29, 2021
Decision date	Jan 10, 2022
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineup, Inc.
Location	Miami, FL, US
Contact	Philippe Laurito
510(k) history	2 submissions · 2 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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