

K092521 ZUMA-CApr 13, 2010
238 days to decisionK092521 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k092521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 18, 2009
Decision date	Apr 13, 2010
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seaspine, Inc.
Location	Vista, CA, US
Contact	ETHEL BERNAL
510(k) history	27 submissions · 27 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092521/> 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 18, 2026