FDA 510(k) Premarket Notification

K092521 ZUMA-C

CLEARED

Apr 13, 2010
238 days to decision

K092521 · 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