

K133218 Crystal ®Dec 10, 2014
418 days to decisionK133218 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k133218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 18, 2013
Decision date	Dec 10, 2014
Days to decision	418 days
Third-party review	No
Summary / Statement	Summary
Other names	Mosaic ®; Vertu ®

APPLICANT

Company	Spinal Elements, Inc.
Location	Carlsbad, CA, US
Contact	JULIE LAMOTHE
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133218/> 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 17, 2026