FDA 510(k) Premarket Notification

K133218 Crystal ®

CLEARED

Dec 10, 2014
418 days to decision

K133218 · 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