

K132596 PROPOSED OPTIMUSApr 11, 2014
235 days to decisionK132596 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k132596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 19, 2013
Decision date	Apr 11, 2014
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Custom Spine, Inc.
Location	Conway, NH, US
Contact	HANAA SHAHIN
510(k) history	12 submissions · 12 cleared · 2005-2015

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