

K161993 Leva® Anterior Interbody SystemNov 22, 2016
126 days to decisionK161993 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k161993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 19, 2016
Decision date	Nov 22, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spine Wave, Inc.
Location	Shelton, CT, US
Contact	Sanja Jahr
510(k) history	57 submissions · 57 cleared · 2004-2025

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