

K150285 Leva(TM) Spacer SystemMar 5, 2015
28 days to decisionK150285 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k150285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 5, 2015
Decision date	Mar 5, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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