

K163246 Leva Anterior Expandable Spacer SystemApr 6, 2017
139 days to decisionK163246 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k163246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 18, 2016
Decision date	Apr 6, 2017
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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