

K153222 Leva Spacer SystemApr 15, 2016
161 days to decisionK153222 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k153222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 6, 2015
Decision date	Apr 15, 2016
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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