

K141980 LEVA (TM) SPACER SYSTEMJan 26, 2015
189 days to decisionK141980 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k141980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 21, 2014
Decision date	Jan 26, 2015
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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