

K132719 STAXX IBL SYSTEMOct 4, 2013
35 days to decisionK132719 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k132719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 30, 2013
Decision date	Oct 4, 2013
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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