

K142101 ABACUS (TM) SPACER SYSTEMOct 23, 2014
83 days to decisionK142101 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k142101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 1, 2014
Decision date	Oct 23, 2014
Days to decision	83 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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