

K261159 Exceed® Biplanar Expandable Interbody SystemMay 29, 2026
51 days to decisionK261159 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k261159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 8, 2026
Decision date	May 29, 2026
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spine Wave, Inc.
Location	Shelton, CT, US
Contact	Ronald Smith
510(k) history	58 submissions · 58 cleared · 2004-2026

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