

K212540 Explorer TO SystemSep 10, 2021
29 days to decisionK212540 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k212540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 12, 2021
Decision date	Sep 10, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SeaSpine Orthopedics Corporation
Location	Carlsbad, CA, US
Contact	Aly Alvarez
510(k) history	66 submissions · 66 cleared · 2016-2025

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