

K203308 Ali Interbody Fusion SystemJan 15, 2021
66 days to decisionK203308 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k203308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 10, 2020
Decision date	Jan 15, 2021
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Raed M. Ali, M.D., Inc.
Location	Newport Coast, CA, US
Contact	Raed Ali
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Allenbridge Consulting
Contact	Kristen Allen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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