

**K212701 Eminent Spine 3D Cervical Interbody Fusion System**Feb 6, 2023  
530 days to decisionK212701 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k212701/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 25, 2021
Decision date	Feb 6, 2023
Days to decision	530 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eminent Spine</b>
Location	Leander, TX, US
Contact	Stephen Courtney
510(k) history	11 submissions · 11 cleared · 2009-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Jalex Medical</b>
Contact	Jennifer Palinchik

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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