

K230219 Eminent Spine 3D Lumbar Interbody Fusion SystemsMay 16, 2023
110 days to decisionK230219 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k230219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 26, 2023
Decision date	May 16, 2023
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eminent Spine, LLC
Location	Plano, TX, US
Contact	Stephen Courtney
510(k) history	4 submissions · 4 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Eminent Spine
Contact	Stephen Courtney

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026