FDA 510(k) Premarket Notification

**CLEARED**

# K230219 Eminent Spine 3D Lumbar Interbody Fusion Systems

May 16, 2023
110 days to decision

K230219 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k230219/

## SUBMISSION DETAILS

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|---|---|
| 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

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|---|---|
| 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