

**K212853 Cervical Stand-Alone System**Nov 5, 2021  
59 days to decisionK212853 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k212853/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 7, 2021
Decision date	Nov 5, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Testing Corp</b>
Contact	Meredith Lee May

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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