

**K242527 The Karma® Fixation System**May 21, 2025  
268 days to decisionK242527 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k242527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Aug 26, 2024
Decision date	May 21, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinal Elements, Inc.</b>
Location	Carlsbad, CA, US
Contact	Cheryl Allen
Website	<a href="https://www.spinalelements.com">https://www.spinalelements.com</a>
510(k) history	48 submissions · 48 cleared · 2007-2026

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