

**K243916 Primus Spinal Fixation System**Feb 21, 2025  
63 days to decisionK243916 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k243916/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 20, 2024
Decision date	Feb 21, 2025
Days to decision	63 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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