

**K160465 Spinal Elements&apos; Spinous Process Plate System**Jul 28, 2016  
160 days to decisionK160465 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k160465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Feb 19, 2016
Decision date	Jul 28, 2016
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinal Elements, Inc.</b>
Location	Carlsbad, CA, US
Contact	Julie Lamothe
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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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