

**K190881 Spinal Elements Navigated Instruments**Dec 19, 2019  
259 days to decisionK190881 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k190881/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 4, 2019
Decision date	Dec 19, 2019
Days to decision	259 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/k190881/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026