

**K131427 LOTUS**Oct 24, 2013  
160 days to decisionK131427 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k131427/>**SUBMISSION DETAILS**

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|                       |                                                |
|-----------------------|------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Appliance, Fixation, Spinal Interlaminar (KWP) |
| Date received         | May 17, 2013                                   |
| Decision date         | Oct 24, 2013                                   |
| 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        | BENJAMIN A KIMBALL                                                          |
| 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/k131427/> 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 17, 2026