

**K161535 SeaSpine® NewPort™ Spinal System**Sep 8, 2016  
97 days to decisionK161535 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k161535/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Jun 3, 2016                                   |
| Decision date         | Sep 8, 2016                                   |
| Days to decision      | 97 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>SeaSpine Orthopedics Corporation</b> |
| Location       | Carlsbad, CA, US                        |
| Contact        | Michelle Willis                         |
| 510(k) history | 66 submissions · 66 cleared · 2016-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161535/> 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 15, 2026