

**K211113 Zavation Spinal System**Jul 12, 2021  
89 days to decisionK211113 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k211113/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Apr 14, 2021                                  |
| Decision date         | Jul 12, 2021                                  |
| Days to decision      | 89 days                                       |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Zavation Medical Products, LLC</b>   |
| Location       | Flowood, MS, US                         |
| Contact        | Katie Motley                            |
| 510(k) history | 30 submissions · 30 cleared · 2018-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211113/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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