

**K132154 CAPSURE PS SYSTEM**Aug 9, 2013  
28 days to decisionK132154 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k132154/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received         | Jul 12, 2013                            |
| Decision date         | Aug 9, 2013                             |
| Days to decision      | 28 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Spine Wave, Inc.</b>                 |
| Location       | Shelton, CT, US                         |
| Contact        | JOSEPH MERCADO                          |
| 510(k) history | 57 submissions · 57 cleared · 2004-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132154/> 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