

K122233 CAPSURE(R) PS SYSTEMOct 11, 2012
77 days to decisionK122233 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k122233/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Jul 26, 2012 |
| Decision date | Oct 11, 2012 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122233/> Data sourced from FDA 510(k) public records (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. - Generated May 18, 2026