

K123461 STAXX(R) IB SYSTEMApr 11, 2013
153 days to decisionK123461 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k123461/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Nov 9, 2012 |
| Decision date | Apr 11, 2013 |
| Days to decision | 153 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123461/> 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