

**K122317 TETRIS II**Aug 29, 2012  
28 days to decisionK122317 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k122317/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Special  |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received         | Aug 1, 2012  |
| Decision date         | Aug 29, 2012   |
| Days to decision      | 28 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Signus Medizintechnik GmbH</b>       |
| Location       | Minneapolis, MN, US                     |
| Contact        | KAREN E WARDEN                          |
| 510(k) history | 23 submissions · 22 cleared · 1999-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122317/> 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 14, 2026