

K153786 PROW FUSION-VJul 11, 2016
193 days to decisionK153786 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k153786/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Dec 31, 2015 |
| Decision date | Jul 11, 2016 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Nlt Spine, Ltd. |
| Location | Washington, Dc, DC, US |
| Contact | Eti Zinger |
| 510(k) history | 8 submissions · 8 cleared · 2011-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153786/> 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 17, 2026