

**K220610 SOLO-L**May 27, 2022  
85 days to decisionK220610 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k220610/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 3, 2022
Decision date	May 27, 2022
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Aurora Spine, Inc.</b>
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	7 submissions · 7 cleared · 2014-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>RQM+</b>
Contact	Lucie Dalet

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220610/> 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 25, 2026