

**K202820 Australis Anterior Lumbar Cage System**Dec 22, 2020  
89 days to decisionK202820 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k202820/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 24, 2020
Decision date	Dec 22, 2020
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Prism Surgical Designs Pty, Ltd.</b>
Location	Milton, AU
Contact	Emma May Young
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Empirical Testing Corp</b>
Contact	Nathan Wright

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/k202820/> 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 June 21, 2026