

**K201079 Aurora® Anterior Lumbar Plate System**Aug 5, 2020  
105 days to decisionK201079 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k201079/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 22, 2020
Decision date	Aug 5, 2020
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201079/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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