FDA 510(k) Premarket Notification

K201079 Aurora® Anterior Lumbar Plate Sytstem

CLEARED

Aug 5, 2020
105 days to decision

K201079 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k201079/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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