FDA 510(k) Premarket Notification

CLEARED

K202820 Australis Anterior Lumbar Cage System

Dec 22, 2020
89 days to decision

K202820 · 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	**Prism Surgical Designs 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