FDA 510(k) Premarket Notification

K213118 Dakota ALIF System

CLEARED

Apr 1, 2022
186 days to decision

K213118 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k213118/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Sep 27, 2021
Decision date	Apr 1, 2022
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Precision Spine, Inc.**
Location	Pear, MS, US
Contact	Michael Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025

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