FDA 510(k) Premarket Notification

K212937 Dakota ALIF Plate System

CLEARED

Nov 4, 2021
50 days to decision

K212937 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k212937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 15, 2021
Decision date	Nov 4, 2021
Days to decision	50 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