FDA 510(k) Premarket Notification

K220324 AccuFit Lateral 2-Hole Plate

CLEARED

Mar 16, 2022
41 days to decision

K220324 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k220324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 3, 2022
Decision date	Mar 16, 2022
Days to decision	41 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	**Element Materials Technology**
Contact	Lisa Ferrara

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