FDA 510(k) Premarket Notification

K242297 Reform Pedicle Screw System

CLEARED

Dec 17, 2024
137 days to decision

K242297 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k242297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 2, 2024
Decision date	Dec 17, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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