FDA 510(k) Premarket Notification

K223529 PressON Spinal Fixation System

CLEARED

May 2, 2023
160 days to decision

K223529 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k223529/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 23, 2022
Decision date	May 2, 2023
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nexus Spine, LLC**
Location	Salt Lake City, UT, US
Contact	Jared Crocker
Website	https://nexusspine.com
510(k) history	17 submissions · 17 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Christine Scifert

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