FDA 510(k) Premarket Notification

K231844 ProMIS™ Fixation System

CLEARED

Jul 7, 2023
15 days to decision

K231844 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k231844/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 22, 2023
Decision date	Jul 7, 2023
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Premia Spine, Ltd.**
Location	Ramat Poleg, IL
Contact	Dorit Winitz
510(k) history	6 submissions · 6 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

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