FDA 510(k) Premarket Notification

K221332 OsteoCentric Spine MIS Pedicle Fastener System

CLEARED

Jul 28, 2022
80 days to decision

K221332 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k221332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 9, 2022
Decision date	Jul 28, 2022
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**OsteoCentric Technologies**
Location	Logan, UT, US
Contact	Todd Evans
510(k) history	11 submissions · 11 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Telos Partners, LLC**
Contact	Roshana Ahmed

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