FDA 510(k) Premarket Notification

K231658 VEOS Spinal Fixation System

CLEARED

Oct 10, 2023
125 days to decision

K231658 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k231658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 7, 2023
Decision date	Oct 10, 2023
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineway**
Location	Ecully, FR
Contact	Maurad Ben Mokhtar
510(k) history	5 submissions · 5 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	**The OrthoMedix Group, Inc.**
Contact	J.D. Webb

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k231658/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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