FDA 510(k) Premarket Notification

K230482 Swedge™ Pedicle Screw Fixation System

CLEARED

Mar 23, 2023
29 days to decision

K230482 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k230482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 22, 2023
Decision date	Mar 23, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Resources, Inc.**
Location	Indian Harbour Beach, FL, US
Contact	Bernie Bedor
510(k) history	4 submissions · 4 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

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