

K252461 Swedge™ Pedicle Screw Fixation System Bezier RodJan 13, 2026
161 days to decisionK252461 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k252461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 5, 2025
Decision date	Jan 13, 2026
Days to decision	161 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	Applied Technical Services (Empirical Technologies)
Contact	Nathan Wright

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

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