

K170045 Swedge™ Pedicle Screw Fixation SystemJun 26, 2017
172 days to decisionK170045 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k170045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 5, 2017
Decision date	Jun 26, 2017
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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