

K181554 Stowe Pedicle Screw SystemJul 27, 2018
44 days to decisionK181554 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k181554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 13, 2018
Decision date	Jul 27, 2018
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Black Box Medical
Location	Midland, TX, US
Contact	Todd Stanaford
510(k) history	2 submissions · 2 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Surgop Support
Contact	Daniel Lanois

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

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