

K243946 EffortMed Spinal Fixation SystemJan 15, 2025
26 days to decisionK243946 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k243946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 20, 2024
Decision date	Jan 15, 2025
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Effortmed, LLC
Location	Coral Springs, FL, US
Contact	Steven Brown
510(k) history	3 submissions · 3 cleared · 2024-2025

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

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