

K251131 Annex® 2 Adjacent Level SystemJun 6, 2025
56 days to decisionK251131 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k251131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 11, 2025
Decision date	Jun 6, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spine Wave, Inc.
Location	Shelton, CT, US
Contact	Ronald Smith
510(k) history	57 submissions · 57 cleared · 2004-2025

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