

K243004 Xpine Spinal Fixation SystemNov 8, 2024
43 days to decisionK243004 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k243004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 26, 2024
Decision date	Nov 8, 2024
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jeil Medical Corporation
Location	Deer Field, IL, US
Contact	Jinwoo Kim Kim
510(k) history	53 submissions · 53 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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