

K254247 OSTEOMNI SPINAL FIXATION SYSTEMFeb 24, 2026
57 days to decisionK254247 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k254247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 29, 2025
Decision date	Feb 24, 2026
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	OSTEOMNI, Inc.
Location	Medley, FL, US
Contact	Gulten Shurdom
Website	https://osteomni.com
510(k) history	1 submissions · 1 cleared · 2026-2026

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