

K243249 TriALTIS™ Spine SystemJan 17, 2025
98 days to decisionK243249 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k243249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 11, 2024
Decision date	Jan 17, 2025
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Jeanette Gardner
510(k) history	96 submissions · 96 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes Spine
Contact	Jeanette Gardner

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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