

K253249 TriALTIS™ Spine SystemOct 21, 2025
22 days to decisionK253249 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k253249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 29, 2025
Decision date	Oct 21, 2025
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Pioneer Surgical Technologies, Inc.
Contact	Sravya Lahari Sripada

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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