

K231479 TriALTIS Spine SystemSep 22, 2023
123 days to decisionK231479 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k231479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 22, 2023
Decision date	Sep 22, 2023
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes Spine
Contact	Denielle Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231479/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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