FDA 510(k) Premarket Notification

K253249 TriALTIS™ Spine System

CLEARED

Oct 21, 2025
22 days to decision

K253249 · 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