FDA 510(k) Premarket Notification

K243249 TriALTIS™ Spine System

CLEARED

Jan 17, 2025
98 days to decision

K243249 · 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