FDA 510(k) Premarket Notification

K242042 TriALTIS™ Spine System

CLEARED

Sep 9, 2024
59 days to decision

K242042 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k242042/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 12, 2024
Decision date	Sep 9, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	Denielle 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