FDA 510(k) Premarket Notification

CLEARED

K251719 Momentum® Posterior Spinal Fixation System

Jul 1, 2025
27 days to decision

K251719 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k251719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 4, 2025
Decision date	Jul 1, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ulrich Medical USA, Inc.**
Location	Plano, TX, US
Contact	Eric Lucas
Website	https://www.ulrichmedical.com
510(k) history	4 submissions · 4 cleared · 2024-2026

Ulrich Medical USA, Inc. is a medical technology company specializing in orthopedic surgical devices. The company operates with a manufacturing facility in Plano, Texas. Ulrich Medical is known for its "Made in Germany" engineering approach and comprehensive spinal surgery solutions. The company has received FDA 510(k) clearances from total submissions. All submissions have focused on orthopedic devices, reflecting the company's specialized expertise in spinal fixation and fusion technologies. First clearance in 2024 and latest clearance in 2026 demonstrate active regulat...

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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