FDA 510(k) Premarket Notification

K260989 Varion Thoracolumbar Fixation System

CLEARED

May 15, 2026
51 days to decision

K260989 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k260989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 25, 2026
Decision date	May 15, 2026
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kyocera Medical Technologies Inc. (KMTI)**
Location	Redlands, CA, US
Contact	Joey Thompson
510(k) history	3 submissions · 3 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Applied Technical Services (Empirical Technologies)**
Contact	Hannah Taggart

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