FDA 510(k) Premarket Notification

K250332 Virage® OCT Spinal Fixation System

CLEARED

Apr 4, 2025
58 days to decision

K250332 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k250332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Feb 5, 2025
Decision date	Apr 4, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Highridge Medical, LLC**
Location	Westminister, CO, US
Contact	Regan Ream
510(k) history	2 submissions · 2 cleared · 2025-2025