FDA 510(k) Premarket Notification

K241487 Interwedge® Standalone Lateral

CLEARED

Oct 2, 2024
131 days to decision

K241487 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k241487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 24, 2024
Decision date	Oct 2, 2024
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Foundation Surgical Group, Inc.**
Location	Scottsdale, AZ, US
Contact	Asher Breverman
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Hannah Taggart

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