FDA 510(k) Premarket Notification

K241468 Vertiwedge® Intraosseous System

CLEARED

Nov 7, 2024
167 days to decision

K241468 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k241468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	May 24, 2024
Decision date	Nov 7, 2024
Days to decision	167 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	Nathan Wright

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