FDA 510(k) Premarket Notification

K242303 MOD-C

CLEARED

Apr 1, 2026
604 days to decision

K242303 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k242303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 5, 2024
Decision date	Apr 1, 2026
Days to decision	604 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthomod, LLC**
Location	Dayton, OH, US
Contact	David Kirschman
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	David Kirschman

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