

K261809 Interwedge® Standalone Lateral

Jul 31, 2026
60 days to decision

K261809 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k261809/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jun 1, 2026
Decision date	Jul 31, 2026
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Foundation Surgical Group
Location	Scottsdale, AZ, US
Contact	Asher Breverman
510(k) history	2 submissions · 2 cleared · 2026-2026