

**K241487 Interwedge® Standalone Lateral**Oct 2, 2024  
131 days to decisionK241487 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k241487/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Technologies</b>
Contact	Hannah Taggart

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241487/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026