

**K250827 aprevo® anterior lumbar interbody fusion device**Jul 7, 2025  
111 days to decisionK250827 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k250827/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 18, 2025
Decision date	Jul 7, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	aprevo® lateral lumbar interbody fusion device; aprevo® anterior lumbar interbody fusion device with interfixation; aprevo® transforaminal lumbar interbody fusion device; aprevo® TLIF-CA Articulating System; aprevo® Cervical ACDF; aprevo® Cervical ACDF-X; aprevo® Cervical ACDF-X No Cams

**APPLICANT**

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Company	<b>Carlsmed, Inc.</b>
Location	La Jolla, CA, US
Contact	Julie Lamothe
510(k) history	20 submissions · 20 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Karen Liu Consulting</b>
Contact	Karen Liu

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250827/> 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