

**K240461 OsteoSinter® EVANS and COTTON wedges and related accessories**Dec 6, 2024  
294 days to decisionK240461 · Product code: PLF · Orthopedic  
Source: <https://www.510kdatabase.net/k240461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Bone Wedge (PLF)
Date received	Feb 16, 2024
Decision date	Dec 6, 2024
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ames Medical Prosthetic Solutions, S.A.U.</b>
Location	Sant Feliu De Llobregat, ES
Contact	Emili Tarrats
510(k) history	1 submissions · 1 cleared · 2024-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240461/>. 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 14, 2026