

**K240368 E3D™-A Interbody System**May 15, 2024  
99 days to decisionK240368 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k240368/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Feb 6, 2024
Decision date	May 15, 2024
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Evolution Spine</b>
Location	Dallas, TX, US
Contact	Todd Wallenstein
Website	<a href="https://evolutionsspine.com">https://evolutionsspine.com</a>
510(k) history	8 submissions · 8 cleared · 2021-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240368/> 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