

K232432 E3D™-A Interbody SystemJan 30, 2024
172 days to decisionK232432 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k232432/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Aug 11, 2023 |
| Decision date | Jan 30, 2024 |
| Days to decision | 172 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Evolution Spine |
| Location | Dallas, TX, US |
| Contact | Todd Wallenstein |
| Website | https://evolutionsspine.com |
| 510(k) history | 8 submissions · 8 cleared · 2021-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232432/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026