FDA 510(k) Premarket Notification

# K232432 E3D™-A Interbody System

**CLEARED**

Jan 30, 2024
172 days to decision

K232432 · 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://evolutionspine.com |
| 510(k) history | 8 submissions · 8 cleared · 2021-2026 |