FDA 510(k) Premarket Notification

**CLEARED**

# K221324 ENZA-O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF)

Mar 30, 2023
328 days to decision

K221324 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k221324/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | May 6, 2022 |
| Decision date | Mar 30, 2023 |
| Days to decision | 328 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Camber Spine Technologies** |
| Location | Newtown Square, PA, US |
| Contact | Noel Hetrick |
| 510(k) history | 17 submissions · 17 cleared · 2013-2024 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **MRC Global, LLC** |
| Contact | Christine Scifert |

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