FDA 510(k) Premarket Notification

# K251459 OneLIF™ Interbody Fusion System

**CLEARED**

Jun 12, 2025
31 days to decision

K251459 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k251459/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | May 12, 2025 |
| Decision date | Jun 12, 2025 |
| Days to decision | 31 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Novapproach Spine, LLC** |
| Location | Alachua, FL, US |
| Contact | Ron Green |
| Website | https://novapproachspine.com |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

Novapproach Spine, LLC develops orthopedic implants and surgical approaches for anterior lumbar spine fusion. Based in Alachua, Florida, the company specializes in simplifying single-position spine surgery through innovative cage and fixation technologies. The company has received FDA 510(k) clearance from total submission. Novapproach Spine focuses exclusively on orthopedic devices, with its first and latest clearance in 2025. The company remains active in regulatory submissions and commercialization. The cleared device, OneLIF™ Interbody Fusion System, supports multiple...

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Empirical Technologies** |
| Contact | Hannah Taggart |

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