

K150765 LDR Spine ROI-C Cervical Cage SystemSep 17, 2015
177 days to decisionK150765 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k150765/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE) |
| Date received | Mar 24, 2015 |
| Decision date | Sep 17, 2015 |
| Days to decision | 177 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ldr Spine USA |
| Location | Austin, TX, US |
| Contact | Brad Strasser |
| 510(k) history | 25 submissions · 25 cleared · 2005-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150765/> 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 17, 2026