

K213118 Dakota ALIF SystemApr 1, 2022
186 days to decisionK213118 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k213118/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Sep 27, 2021 |
| Decision date | Apr 1, 2022 |
| Days to decision | 186 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Precision Spine, Inc. |
| Location | Pear, MS, US |
| Contact | Michael Dawson |
| 510(k) history | 24 submissions · 24 cleared · 2014-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Empirical Testing Corp |
| Contact | Nathan Wright |

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

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