

K171046 SeaSpine Cambria SystemJul 7, 2017
91 days to decisionK171046 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k171046/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Apr 7, 2017 |
| Decision date | Jul 7, 2017 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | SeaSpine Orthopedics Corporation |
| Location | Carlsbad, CA, US |
| Contact | Gina Flores |
| 510(k) history | 66 submissions · 66 cleared · 2016-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171046/> 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 15, 2026