

K200115 Cavetto-SA Cervical Cage SystemSep 24, 2020
247 days to decisionK200115 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k200115/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE) |
| Date received | Jan 21, 2020 |
| Decision date | Sep 24, 2020 |
| Days to decision | 247 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Neurostructures, Inc. |
| Location | Colorado Springs, CO, US |
| Contact | Moti Altarac |
| 510(k) history | 15 submissions · 15 cleared · 2014-2020 |

REGULATORY CONSULTANT

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|-----------------|-------------------------------|
| 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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