

K182195 Arco™-SA Lumbar Cage SystemNov 9, 2018
87 days to decisionK182195 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k182195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 14, 2018
Decision date	Nov 9, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Empirical Consulting
Contact	Meredith Lee May

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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