FDA 510(k) Premarket Notification

CLEARED

K182195 Arco™-SA Lumbar Cage System

Nov 9, 2018
87 days to decision

K182195 · 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