

K190291 Addivation Medical Cervical Interbody SystemJul 30, 2019
169 days to decisionK190291 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k190291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 11, 2019
Decision date	Jul 30, 2019
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Addivation Medical, LLC
Location	Monmouth Beach, NJ, US
Contact	Gregory Stebbins
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Linda Braddon

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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