

K191812 ADI Cervical Interbody Fusion DeviceOct 24, 2019
111 days to decisionK191812 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k191812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 5, 2019
Decision date	Oct 24, 2019
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Additive Device, Inc. (Adi) D/B/A Restor3D
Location	Durham, NC, US
Contact	Nathan Evans
510(k) history	2 submissions · 2 cleared · 2019-2019

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