

K211111 SureMAX-SA Cervical Standalone SystemJul 16, 2021
93 days to decisionK211111 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k211111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Apr 14, 2021
Decision date	Jul 16, 2021
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Additive Implants, Inc.
Location	Phoenix, AZ, US
Contact	Jeff Horn
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Backroads Consulting
Contact	Karen E Warden

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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