

K152972 Amendia Stand-Alone Cervical SystemJan 14, 2016
98 days to decisionK152972 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k152972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 8, 2015
Decision date	Jan 14, 2016
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amendia, Inc.
Location	Apple Valley, MN, US
Contact	KRISTEN ALLEN
510(k) history	16 submissions · 16 cleared · 2009-2016

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