

K151310 Amendia Interbody Fusion DevicesJan 6, 2016
233 days to decisionK151310 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k151310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 18, 2015
Decision date	Jan 6, 2016
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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