

K151322 Amendia Interbody Fusion DevicesSep 10, 2015
115 days to decisionK151322 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k151322/>**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	Sep 10, 2015
Days to decision	115 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026