FDA 510(k) Premarket Notification

K151322 Amendia Interbody Fusion Devices

CLEARED

Sep 10, 2015
115 days to decision

K151322 · 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