FDA 510(k) Premarket Notification

K160291 Optimus ALIF System

CLEARED

Feb 18, 2016
15 days to decision

K160291 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k160291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Feb 3, 2016
Decision date	Feb 18, 2016
Days to decision	15 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