FDA 510(k) Premarket Notification

# K151310 Amendia Interbody Fusion Devices

**CLEARED**

Jan 6, 2016
233 days to decision

K151310 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151310/

## SUBMISSION DETAILS

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|---|---|
| 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

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