FDA 510(k) Premarket Notification

# K131242 ARDIS INTERBODY SYSTEM

**CLEARED**

Sep 3, 2013
125 days to decision

K131242 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k131242/

## 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 1, 2013 |
| Decision date | Sep 3, 2013 |
| Days to decision | 125 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Zimmer Spine, Inc.** |
| Location | Minneapolis, MN, US |
| Contact | JON GILBERT |
| 510(k) history | 38 submissions · 35 cleared · 2004-2016 |