FDA 510(k) Premarket Notification

# K170399 Endoskeleton TO Interbody Fusion Device (IBD)

**CLEARED**

Jul 6, 2017
147 days to decision

K170399 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k170399/

## 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 | Feb 9, 2017 |
| Decision date | Jul 6, 2017 |
| Days to decision | 147 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Titan Spine, LLC** |
| Location | Mequon, WI, US |
| Contact | Jane Rodd |
| 510(k) history | 14 submissions · 14 cleared · 2008-2018 |