FDA 510(k) Premarket Notification

# K180990 TirboLOX-L Lumbar IBFD

**CLEARED**

Aug 13, 2018
119 days to decision

K180990 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k180990/

## 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 | Apr 16, 2018 |
| Decision date | Aug 13, 2018 |
| Days to decision | 119 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Captiva Spine, Inc.** |
| Location | Pleasant Grove, UT, US |
| Contact | Jackie Ferro |
| 510(k) history | 8 submissions · 8 cleared · 2009-2020 |