FDA 510(k) Premarket Notification

# K124012 INFILL OBLIQUE TLIF DEVICE

**CLEARED**

Jun 4, 2013
159 days to decision

K124012 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k124012/

## 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 | Dec 27, 2012 |
| Decision date | Jun 4, 2013 |
| Days to decision | 159 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Pinnacle Spine Group, LLC** |
| Location | Dallas, TX, US |
| Contact | Rebecca K Pine |
| 510(k) history | 12 submissions · 12 cleared · 2011-2017 |