FDA 510(k) Premarket Notification

# K181380 LnK Lumbar Interbody Fusion Cage System

**CLEARED**

Sep 11, 2018
110 days to decision

K181380 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181380/

## 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 24, 2018 |
| Decision date | Sep 11, 2018 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **L & K Biomed Co., Ltd.** |
| Location | Yongin-Si, KR |
| Contact | Jihyeon Seo |
| Website | https://www.lkbiomed.com |
| 510(k) history | 54 submissions · 54 cleared · 2010-2026 |