FDA 510(k) Premarket Notification

# K190364 CancelleX Porous Titanium Lumbar Interbody Device

**CLEARED**

Apr 18, 2019
62 days to decision

K190364 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190364/

## 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 15, 2019 |
| Decision date | Apr 18, 2019 |
| Days to decision | 62 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Xenco Medical, LLC** |
| Location | San Diego, CA, US |
| Contact | Jason Haider |
| 510(k) history | 16 submissions · 16 cleared · 2014-2025 |