FDA 510(k) Premarket Notification

**CLEARED**

# K181644 EIT Cellular Titanium® Lumbar Cage LLIF

Oct 12, 2018
112 days to decision

K181644 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181644/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Jun 22, 2018 |
| Decision date | Oct 12, 2018 |
| Days to decision | 112 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Eit Emerging Implant Technologies GmbH** |
| Location | Wurmlingen, DE |
| Contact | Barbara Wirth |
| 510(k) history | 5 submissions · 5 cleared · 2017-2020 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Musculoskeletal Clinical Regulatory Advisers, LLC** |
| Contact | Justin Eggleton |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181644/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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