

K201605 EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF CageJul 15, 2020
30 days to decisionK201605 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k201605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 15, 2020
Decision date	Jul 15, 2020
Days to decision	30 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	Depuy Synthes Spine
Contact	Christine Cahillane

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

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