

K213641 MONDRIAN ALIF Cage with Supplementary Fixation PlateSep 15, 2022
301 days to decisionK213641 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k213641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 18, 2021
Decision date	Sep 15, 2022
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ctl Medical Corporation
Location	Addison, TX, US
Contact	Sean Suh
510(k) history	14 submissions · 14 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Omni Strategic Solutions, LLC
Contact	Dhaval Saraiya

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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