

**K233947 KLIMIT™ Expandable Lumbar Interbody Fusion (LIF)  
Cage System**Oct 10, 2024  
301 days to decisionK233947 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k233947/>**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	Dec 14, 2023
Decision date	Oct 10, 2024
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Omnee Strategic Solutions, Inc.</b>
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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