

**K231715 MONDRIAN™ Anterior Lumbar Plate System**Jan 26, 2024  
227 days to decisionK231715 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k231715/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 13, 2023
Decision date	Jan 26, 2024
Days to decision	227 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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