

K231359 RODIN™ Expandable Lumbar Cage SystemJun 9, 2023
30 days to decisionK231359 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k231359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 10, 2023
Decision date	Jun 9, 2023
Days to decision	30 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	Omnee Strategic Solutions, Inc.
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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