

K211785 CASSATT™ SIJ Fixation SystemOct 17, 2022
495 days to decisionK211785 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k211785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jun 9, 2021
Decision date	Oct 17, 2022
Days to decision	495 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	RQMIS, Inc.
Contact	Barry Sands

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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