

K211496 TransLoc 3DJul 27, 2022
440 days to decisionK211496 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k211496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	May 13, 2021
Decision date	Jul 27, 2022
Days to decision	440 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foundation Fusion Solutions, LLC (Db a Cornerloc)
Location	Tulsa, OK, US
Contact	Robert Compton
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Watershed Idea Foundry
Contact	Jeffrey Brittan

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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