

K212962 TRELIS™ SI Joint Fusion SystemApr 11, 2022
207 days to decisionK212962 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k212962/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Sep 16, 2021
Decision date	Apr 11, 2022
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofundamentals, LLC
Location	Medford, MA, US
Contact	Matthew Palmer
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212962/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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