

K232605 Sacrix® Sacroiliac Joint Fusion Device System, Inspan® ScrewLES Fusion System, Invue® MAX™ + Invue Inset Anterior Cervical Plate System, and FacetFuse® Screw Fixation SystemSep 28, 2023
31 days to decisionK232605 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k232605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Aug 28, 2023
Decision date	Sep 28, 2023
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lesspine Innovations
Location	Malden, MA, US
Contact	Vito Lore
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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