CLEARED

K232605 Sacrix® Sacroiliac Joint Fusion Device System, Inspan® ScrewLES Fusion System, Invue® MAX™ + Invue Inset Anterior Cervical Plate System, and FacetFuse® Screw Fixation System

Sep 28, 2023
31 days to decision

K232605 · 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