

K240505 Eminent Spine SI Screw SystemJun 4, 2024
104 days to decisionK240505 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k240505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Feb 21, 2024
Decision date	Jun 4, 2024
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eminent Spine, LLC
Location	Plano, TX, US
Contact	Stephen Courtney
510(k) history	4 submissions · 4 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Jalex Medical
Contact	Chhavy Tep-Cullison

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/k240505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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