

K252322 Siros-X SystemOct 22, 2025
89 days to decisionK252322 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k252322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jul 25, 2025
Decision date	Oct 22, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genesys Spine
Location	Austin, TX, US
Contact	Bill Sowers
510(k) history	31 submissions · 31 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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