

K252088 Firebird SI Navigation SystemOct 31, 2025
121 days to decisionK252088 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k252088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 2, 2025
Decision date	Oct 31, 2025
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix US, LLC
Location	Lweisville, TX, US
Contact	Kendal Moulton
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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