

K253611 Falco Fusion SystemJan 29, 2026
72 days to decisionK253611 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k253611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Nov 18, 2025
Decision date	Jan 29, 2026
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mcnicoll Surgical, Inc.
Location	Quebec City, CA
Contact	Etienne Robichaud
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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