

**K250679 FFX Facet Fixation System**Dec 4, 2025  
273 days to decisionK250679 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k250679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Mar 6, 2025
Decision date	Dec 4, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sc Medica</b>
Location	Strasbourg, FR
Contact	Camille Srour
510(k) history	3 submissions · 3 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Palmer Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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