

K252153 FFX Facet Fixation SystemOct 16, 2025
99 days to decisionK252153 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k252153/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Facet Screw Spinal Device (MRW) |
| Date received | Jul 9, 2025 |
| Decision date | Oct 16, 2025 |
| Days to decision | 99 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

REGULATORY CONSULTANT

| | |
|-----------------|------------------|
| Consulting firm | Mcra, LLC |
| Contact | Justin Eggleton |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05645497**

Evaluation of the Efficacy and Safety of the FACET FIXation Implant.

| | |
|-------------------|---|
| Status | Unknown - <i>No results published to ClinicalTrials.gov</i> |
| Enrollment | 116 patients (estimated) |
| Study sites | 1 site |
| Condition studied | Degenerative Lumbar Spinal Stenosis |
| Study type | Observational |
| Completion date | Apr 30, 2023 |
| Sponsor | SC Medica (Industry) |

Primary outcome**The rate of fusion**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05645497
