

K250247 panaSla SI Fusion SystemJul 9, 2025
163 days to decisionK250247 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k250247/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sacroiliac Joint Fixation (OUR) |
| Date received | Jan 27, 2025 |
| Decision date | Jul 9, 2025 |
| Days to decision | 163 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Wenzel Spine, Inc. |
| Location | Austin, TX, US |
| Contact | William Wilson |
| 510(k) history | 6 submissions · 6 cleared · 2013-2025 |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250247/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026