

K212903 SIMPACT Sacroiliac Joint Fixation SystemDec 15, 2021
93 days to decisionK212903 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k212903/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sacroiliac Joint Fixation (OUR) |
| Date received | Sep 13, 2021 |
| Decision date | Dec 15, 2021 |
| Days to decision | 93 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Life Spine, Inc. |
| Location | Hoffman Estates, IL, US |
| Contact | Angela Batker |
| 510(k) history | 82 submissions · 82 cleared · 2011-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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