

K223819 SI-Cure Sacroiliac Joint Fusion SystemJan 18, 2023
28 days to decisionK223819 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k223819/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Sacroiliac Joint Fixation (OUR) |
| Date received | Dec 21, 2022 |
| Decision date | Jan 18, 2023 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Alevio, LLC |
| Location | Birmingham, AL, US |
| Contact | Trey Robbins |
| 510(k) history | 2 submissions · 2 cleared · 2023-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Empirical Technologies |
| Contact | Nathan Wright |

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/k223819/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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