

K232211 REUNION Sacroiliac Joint Fusion SystemOct 24, 2023
90 days to decisionK232211 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k232211/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sacroiliac Joint Fixation (OUR) |
| Date received | Jul 26, 2023 |
| Decision date | Oct 24, 2023 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Astura Medical |
| Location | Carlsbad, CA, US |
| Contact | Parker Kelch |
| 510(k) history | 21 submissions · 21 cleared · 2016-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232211/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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