

K222448 UNITY Sacroiliac Joint Fixation SystemOct 13, 2022
59 days to decisionK222448 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k222448/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sacroiliac Joint Fixation (OUR) |
| Date received | Aug 15, 2022 |
| Decision date | Oct 13, 2022 |
| Days to decision | 59 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dio Medical Corporation |
| Location | East Norriton, PA, US |
| Contact | Milan George |
| 510(k) history | 4 submissions · 4 cleared · 2022-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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