

**K222605 iFuse TORQ® Implant System**Sep 29, 2022  
31 days to decisionK222605 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k222605/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Sacroiliac Joint Fixation (OUR)    |
| Date received         | Aug 29, 2022                       |
| Decision date         | Sep 29, 2022                       |
| Days to decision      | 31 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>SI-BONE, Inc.</b>                                  |
| Location       | Santa Clara, CA, US                                   |
| Contact        | Meirav Harsat   |
| Website        | <a href="https://si-bone.com">https://si-bone.com</a> |
| 510(k) history | 32 submissions · 32 cleared · 2008-2026               |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222605/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026