

**K253488 iFuse INTRA Ti™ Implant System**Feb 11, 2026  
110 days to decisionK253488 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k253488/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Oct 24, 2025
Decision date	Feb 11, 2026
Days to decision	110 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	Jayasri Prabakaran
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/k253488/> 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