

**K123850 IFUSE IMPLANT SYSTEM**Apr 1, 2013  
108 days to decisionK123850 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k123850/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 14, 2012
Decision date	Apr 1, 2013
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SI-BONE, Inc.</b>
Location	Santa Clara, CA, US
Contact	CINDY DOMECUS
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/k123850/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026