

**K151718 iFuse Implant System**Oct 29, 2015  
126 days to decisionK151718 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k151718/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jun 25, 2015
Decision date	Oct 29, 2015
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151718/> 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 17, 2026