

K152681 iFuse Implant System(R)Mar 1, 2016
165 days to decisionK152681 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k152681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Sep 18, 2015
Decision date	Mar 1, 2016
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152681/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026