

K253094 iFuse Bedrock Granite Implant System

Oct 9, 2025
16 days to decision

K253094 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k253094/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Sep 23, 2025
Decision date	Oct 9, 2025
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253094/> 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 14, 2026