

K220195 iFuse Bedrock Granite™ Implant SystemMay 26, 2022
122 days to decisionK220195 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k220195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jan 24, 2022
Decision date	May 26, 2022
Days to decision	122 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	Meirav Harsat
Website	https://si-bone.com
510(k) history	32 submissions · 32 cleared · 2008-2026

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