

K172268 iFuse Implant System- iFuse NavigationOct 31, 2017
96 days to decisionK172268 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k172268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 27, 2017
Decision date	Oct 31, 2017
Days to decision	96 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

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