

**K190230 iFuse Implant System®**Apr 3, 2019  
56 days to decisionK190230 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k190230/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Feb 6, 2019
Decision date	Apr 3, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Domecus Consulting Services, LLC</b>
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190230/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026