FDA 510(k) Premarket Notification

K190230 iFuse Implant System®

CLEARED

Apr 3, 2019
56 days to decision

K190230 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k190230/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Domecus Consulting Services, LLC**
Contact	Cindy Domecus

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