FDA 510(k) Premarket Notification

K092375 MODIFICATION TO SI JOINT FUSION SYSTEM

CLEARED

Sep 4, 2009
30 days to decision

K092375 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k092375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Aug 5, 2009
Decision date	Sep 4, 2009
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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