FDA 510(k) Premarket Notification

K152681 iFuse Implant System(R)

CLEARED

Mar 1, 2016
165 days to decision

K152681 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k152681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Sep 18, 2015
Decision date	Mar 1, 2016
Days to decision	165 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