FDA 510(k) Premarket Notification

K222605 iFuse TORQ® Implant System

CLEARED

Sep 29, 2022
31 days to decision

K222605 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k222605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Aug 29, 2022
Decision date	Sep 29, 2022
Days to decision	31 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