FDA 510(k) Premarket Notification

K222512 Integrity-SI Fusion System

CLEARED

Sep 12, 2022
24 days to decision

K222512 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k222512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Aug 19, 2022
Decision date	Sep 12, 2022
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**OsteoCentric Technologies**
Location	Logan, UT, US
Contact	Todd Evans
510(k) history	11 submissions · 11 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Telos Partners, LLC**
Contact	Ken Riordan

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