FDA 510(k) Premarket Notification

K221047 SILO TFX MIS Sacroiliac Joint Fixation System

CLEARED

Oct 3, 2022
178 days to decision

K221047 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k221047/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Apr 8, 2022
Decision date	Oct 3, 2022
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aurora Spine, Inc.**
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	7 submissions · 7 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Samuel Pollard

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