FDA 510(k) Premarket Notification

K220274 Kisar Stratford SI Screw System

CLEARED

Apr 24, 2023
448 days to decision

K220274 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k220274/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jan 31, 2022
Decision date	Apr 24, 2023
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anjali Investments L.L.C**
Location	Lutherville, MD, US
Contact	Amit Patel
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical, LLC**
Contact	Jennifer Palinchik

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