FDA 510(k) Premarket Notification

K213815 SiJoin®T3

CLEARED

Mar 29, 2023
477 days to decision

K213815 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k213815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 7, 2021
Decision date	Mar 29, 2023
Days to decision	477 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vgi Medical, Inc.**
Location	Largo, FL, US
Contact	Tov Vestgaarden
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Silver Pine Consulting**
Contact	Richard Jansen

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