

K213815 SiJoin®T3Mar 29, 2023
477 days to decisionK213815 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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