

K250647 Slimmetry+ SystemJul 29, 2025
147 days to decisionK250647 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k250647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Mar 4, 2025
Decision date	Jul 29, 2025
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sivantage
Location	Tampa, FL, US
Contact	Brian Ranft
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Michael Coladonato

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/k250647/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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