FDA 510(k) Premarket Notification

K250247 panaSIa SI Fusion System

CLEARED

Jul 9, 2025
163 days to decision

K250247 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k250247/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jan 27, 2025
Decision date	Jul 9, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wenzel Spine, Inc.**
Location	Austin, TX, US
Contact	William Wilson
510(k) history	6 submissions · 6 cleared · 2013-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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