

K242431 Omnia Medical PsiF DNA™ SystemJun 6, 2025
294 days to decisionK242431 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k242431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Aug 16, 2024
Decision date	Jun 6, 2025
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omnia Medical, LLC
Location	Morgantown, WV, US
Contact	Troy Schifano
Website	https://www.omniamedical.com
510(k) history	11 submissions · 11 cleared · 2017-2025

Omnia Medical, LLC is an orthopedic implant company based in Morgantown, West Virginia. The company develops innovative surgical implants and instrumentation focused on spinal fusion and joint stabilization procedures. Omnia Medical's product portfolio emphasizes reproducible surgical techniques and improved patient outcomes. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2017. All submissions have focused on orthopedic devices. The most recent clearance was in 2025, demonstrating continued regulatory activity and produc...

REGULATORY CONSULTANT

Consulting firm	Sagemar Medical, LLC
Contact	Jennifer Palinchik

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

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Device record: <https://www.510kdatabase.net/k242431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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