

K212612 Omnia Medical TiBrid-SCNov 15, 2022
455 days to decisionK212612 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k212612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 17, 2021
Decision date	Nov 15, 2022
Days to decision	455 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omnia Medical, LLC
Location	Morgantown, WV, US
Contact	Morgan Hill
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...

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Device record: <https://www.510kdatabase.net/k212612/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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