

**K203207 Omnia Medical TiBrid-SA**Dec 23, 2020  
54 days to decisionK203207 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k203207/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Oct 30, 2020
Decision date	Dec 23, 2020
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Omnia Medical, LLC</b>
Location	Morgantown, WV, US
Contact	Troy Schifano
Website	<a href="https://www.omniamedical.com">https://www.omniamedical.com</a>
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...

---