

K191778 Omnia Medical VBRAug 28, 2019
57 days to decisionK191778 · Product code: **PLR** · Orthopedic
Source: <https://www.510kdatabase.net/k191778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinal Vertebral Body Replacement Device - Cervical (PLR)
Date received	Jul 2, 2019
Decision date	Aug 28, 2019
Days to decision	57 days
Third-party review	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...
