FDA 510(k) Premarket Notification

CLEARED

K223321 Omnia Medical Coupler-C Anterior Cervical Plate

Mar 13, 2023
133 days to decision

K223321 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k223321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Oct 31, 2022
Decision date	Mar 13, 2023
Days to decision	133 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	**Jalex Medical**
Contact	Jennifer Palinchik

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