FDA 510(k) Premarket Notification

K253326 Oxiplex

CLEARED

May 1, 2026
213 days to decision

K253326 · Product code: **QVL** · Orthopedic
Source: https://www.510kdatabase.net/k253326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Absorbable Gel For Intraoperative Use In Spine Surgery (QVL)
Date received	Sep 30, 2025
Decision date	May 1, 2026
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fziomed, Inc.**
Location	San Luis Obispo, CA, US
Contact	Paul Mraz
Website	https://fziomed.com
510(k) history	2 submissions · 1 cleared · 2025-2026

Fziomed, Inc. is a global leader in postsurgical adhesion prevention. The company develops and manufactures innovative absorbable gel barrier products designed to reduce postoperative adhesion formation across multiple surgical specialties. Fziomed operates with a manufacturing facility in San Luis Obispo, California, and has treated over one million patients worldwide since 2002. The company has received FDA 510(k) clearance from total submissions. All submissions focus on Orthopedic devices. The most recent clearance was in 2026, demonstrating continued regulatory activ...

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Lisa Pritchard

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