

K241357 XT3 SystemJan 22, 2025
253 days to decisionK241357 · Product code: **JDW** · Orthopedic
Source: <https://www.510kdatabase.net/k241357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Threaded (JDW)
Date received	May 14, 2024
Decision date	Jan 22, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biodynamik, Inc.
Location	Lake Forest, CA, US
Contact	Johnny Chen
Website	https://biodynamik.com
510(k) history	2 submissions · 2 cleared · 2025-2026

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