

K243452 Orthoscan VERSA Mini C-ArmJan 14, 2025
68 days to decisionK243452 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k243452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Nov 7, 2024
Decision date	Jan 14, 2025
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ziehm-Orthoscan, Inc.
Location	Scottsdale, AZ, US
Contact	Kevin Bridgman
510(k) history	3 submissions · 3 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243452/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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