

K241567 MC2 Portable X-ray SystemDec 6, 2024
189 days to decisionK241567 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k241567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	May 31, 2024
Decision date	Dec 6, 2024
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxos Medical
Location	Atlanta, GA, US
Contact	Dhruv Vishwakarma
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Powers Regulatory Consulting
Contact	Dhruv Vishwakarma

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

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