FDA 510(k) Premarket Notification

CLEARED

K251004 Dual-Mode Mobile C-Arm (Geelin500A, Geelin500M)

Nov 6, 2025
219 days to decision

K251004 · Product code: **OXO** · Radiology
Source: https://www.510kdatabase.net/k251004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Apr 1, 2025
Decision date	Nov 6, 2025
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hefei Chimed Intelligent Machine Co., Ltd.**
Location	Hefei, CN
Contact	Min Li
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Grzan Medical Technology (Shenzhen) Co., Ltd.**
Contact	Garen Liu

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