FDA 510(k) Premarket Notification

K240828 OEC One ASD

CLEARED

Dec 27, 2024
276 days to decision

K240828 · Product code: **OXO** · Radiology
Source: https://www.510kdatabase.net/k240828/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Mar 26, 2024
Decision date	Dec 27, 2024
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Hualun Medical Systems Co. , Ltd.**
Location	Beijing, CN
Contact	Lifeng Wang
510(k) history	12 submissions · 12 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**GE Healthcare**
Contact	Michelle Huettner

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