

**K240828 OEC One ASD**Dec 27, 2024  
276 days to decisionK240828 · Product code: **OXO** · Radiology  
Source: <https://www.510kdatabase.net/k240828/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>GE Healthcare</b>
Contact	Michelle Huettner

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

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