

K253269 OEC One CFDNov 26, 2025
58 days to decisionK253269 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k253269/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Image-intensified Fluoroscopic X-ray System, Mobile (OXO) |
| Date received | Sep 29, 2025 |
| Decision date | Nov 26, 2025 |
| Days to decision | 58 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253269/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026