

**K141672 DIGIARC 100AU+**Jul 31, 2014  
38 days to decisionK141672 · Product code: **OXO** · Radiology  
Source: <https://www.510kdatabase.net/k141672/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Special   |
| Device classification | Image-intensified Fluoroscopic X-ray System, Mobile (OXO) |
| Date received         | Jun 23, 2014  |
| Decision date         | Jul 31, 2014  |
| Days to decision      | 38 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Beijing East Whale Imaging Technology Co., Ltd.</b> |
| Location       | Beijing, CN  |
| Contact        | JUNE LI  |
| 510(k) history | 6 submissions · 6 cleared · 2013-2017                  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141672/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026