

K163429 B6Jan 4, 2017
28 days to decisionK163429 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k163429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Dec 7, 2016
Decision date	Jan 4, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beijing East Whale Imaging Technology Co., Ltd.
Location	Beijing, CN
Contact	Sharon Fan
510(k) history	6 submissions · 6 cleared · 2013-2017

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