

K182626 OEC OneNov 16, 2018
53 days to decisionK182626 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k182626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Sep 24, 2018
Decision date	Nov 16, 2018
Days to decision	53 days
Third-party review	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

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