

K203346 OEC 3DMar 5, 2021
112 days to decisionK203346 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k203346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Nov 13, 2020
Decision date	Mar 5, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Oec Medical Systems, Inc.
Location	Salt Lake City, UT, US
Contact	Kenny M. Bello
510(k) history	11 submissions · 11 cleared · 2004-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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