

**K192819 OEC Elite**Nov 8, 2019  
38 days to decisionK192819 · Product code: **OXO** · Radiology  
Source: <https://www.510kdatabase.net/k192819/>**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	Oct 1, 2019
Decision date	Nov 8, 2019
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192819/> 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 27, 2026