

**K041213 3DSCOPE**Jul 22, 2004  
73 days to decisionK041213 · Product code: **OXO** · Radiology  
Source: <https://www.510kdatabase.net/k041213/>**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	May 10, 2004
Decision date	Jul 22, 2004
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Direx Systems Corp.</b>
Location	Natick, MA, US
Contact	LARISA GERSHTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012

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