

**K050996 O-ARM IMAGING SYSTEM**May 5, 2005  
15 days to decisionK050996 · Product code: **OXO** · Radiology  
Source: <https://www.510kdatabase.net/k050996/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Apr 20, 2005
Decision date	May 5, 2005
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Breakaway Imaging, LLC</b>
Location	Littleton, MA, US
Contact	WOLFGANG KRULL
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050996/> 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 18, 2026