

**K920539 ORWO X-RAY FILM**Jun 30, 1992  
146 days to decisionK920539 · Product code: **IWZ** · Radiology  
Source: <https://www.510kdatabase.net/k920539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Film, Radiographic (IWZ)
Date received	Feb 5, 1992
Decision date	Jun 30, 1992
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Burkhart Roentgen Intl., Inc.</b>
Location	Pinellas Park, FL, US
Contact	NORMAN JACKVONY
510(k) history	3 submissions · 3 cleared · 1992-1992

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