

**K981466 XR-910**Jul 14, 1998  
82 days to decisionK981466 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k981466/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Apr 23, 1998
Decision date	Jul 14, 1998
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imaging Sciences Intl., Inc.</b>
Location	Gwynedd, PA, US
Contact	ROBERT E HAY
510(k) history	7 submissions · 7 cleared · 1993-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981466/> 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