

**K081073 HDR VISION, VISION HDR, HD R/F, UROMAT HD R/F**Dec 5, 2008  
234 days to decisionK081073 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k081073/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Apr 15, 2008
Decision date	Dec 5, 2008
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pausch, LLC</b>
Location	Tinton Falls, NJ, US
Contact	JUSTIN TICE
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081073/> 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 17, 2026