

**K123644 VIZION + DR**Jan 11, 2013  
46 days to decisionK123644 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k123644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 26, 2012
Decision date	Jan 11, 2013
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Viztek, LLC</b>
Location	Naples, FL, US
Contact	DANIEL KAMM, P.E.
510(k) history	6 submissions · 6 cleared · 2011-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123644/> 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 16, 2026