

**K100625 REALEYE MODEL VCPS**Jan 21, 2011  
323 days to decisionK100625 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k100625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 4, 2010
Decision date	Jan 21, 2011
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Navotek Medical, Ltd.</b>
Location	Philedelphia, PA, US
Contact	STEVEN B DATLOF, M.D., J.D.
510(k) history	2 submissions · 2 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100625/> 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