

**K003236 RETINADX**Nov 2, 2000  
16 days to decisionK003236 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k003236/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 17, 2000
Decision date	Nov 2, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Regulatory Associates, Inc.</b>
Location	Lakewood, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003236/> 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 June 29, 2026