

**K133892 IVUE 500**Mar 19, 2014  
89 days to decisionK133892 · Product code: **HLI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k133892/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Dec 20, 2013
Decision date	Mar 19, 2014
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optovue, Inc.</b>
Location	Fremont, CA, US
Contact	MICHAEL J SARRASIN
510(k) history	16 submissions · 16 cleared · 2006-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133892/> 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 26, 2026