

K121739 IVUE WITH NORMATIVE DATABASEJan 18, 2013
219 days to decisionK121739 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k121739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Jun 13, 2012
Decision date	Jan 18, 2013
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optovue, Inc.
Location	Fremont, CA, US
Contact	Azimun Jamal
510(k) history	16 submissions · 16 cleared · 2006-2022

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