

**K163475 iVue**Jun 9, 2017  
179 days to decisionK163475 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k163475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Dec 12, 2016
Decision date	Jun 9, 2017
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optovue, Inc.</b>
Location	Fremont, CA, US
Contact	Edward J. Sinclair
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/k163475/> 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